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 <p>UCSF Medical Center Clinical Laboratories</p>	<p>Point of Care Testing</p>
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HemoCue Hb 201 DM Procedure

I. PURPOSE

The HemoCue Hb 201 DM is a portable analyzer used for the quantitative determination of hemoglobin in whole blood at the patient's bedside.

II. PRINCIPLE

The HemoCue Hb 201 DM system consists of a specially designed Analyzer with specially designed microcuvettes containing dry reagents. The microcuvette serves as a pipette, reaction vessel and as a measuring microcuvette. The hemoglobin measurement takes place in the Analyzer, which follows the progress of the reaction until the end point has been reached. The system is factory calibrated against the hemoglobincyanide method, the international reference method. The optical eye of the microcuvette contains the dried testing reagents. Ten microliters of blood are drawn into the optical eye by capillary action and spontaneously mixed with the reagents. Hemoglobin is converted to azidmethemoglobin. The HemoCue reader tunes the reaction and displays hemoglobin results in grams per deciliter.

III. SCOPE

This procedure is for the Clinical Laboratories and UCSF POCT.

IV. PERSONNEL

Intended for use by clinical personnel who have been trained and demonstrated competency in this procedure.

V. EQUIPMENT

1. HemoCue Hb 201 DM Photometer
 2. HemoCue Hb 201 microcuvettes
 3. R + D liquid quality controls, [Level 1](#) and [Level 3](#)
 4. HemoCue 201 DM docking station: the Primary connects to a specified PC, the secondary docking stations connect to the Primary.
 5. HemoCue 201 DM Software.
 6. Sharps container
 7. Gloves
 8. Finger stick lancet
 9. Cotton swabs
 10. Kimwipes
 11. Warm water
 12. Refrigerator for liquid control storage
 13. HemoCue Cleaner (Optional)
1. HemoCue Hb 201 DM Photometer, HemoCue AB, Sweden
 - a. The analyzer is powered by a rechargeable battery which is plugged in to a standard electrical outlet via the AC adapter.
 - i. The rechargeable battery is located in the battery compartment on the bottom of the analyzer.
 - ii. Recharge the battery by gently sliding the Analyzer into the docking station until it locks into place.
 - iii. A steady green light from the docking station indicates that the docking station is receiving power and that the Battery is fully charged. A flashing green light indicates the Analyzer is charging.
 - b. To turn the analyzer on:
 - i. First pull the black cuvette holder out of the Analyzer (also referred to as the LOADING position.) Press the On/Off button located on the face of the Analyzer. It is the black oblong shaped button with a white dot within a white circle.
 - ii. The HemoCue logo and version number of the software will be displayed.
 - iii. The screen will display “Please Wait Selftesting...”. This takes 20 seconds. If the cuvette holder is not pulled out, the screen will read “Please Pull out The Cuvette Holder”. During the self-test, the Analyzer automatically verifies the performance of the optronic unit.
 - iv. The Analyzer is set to require a valid Operator user ID either by the Barcode Scanner or manual entry.
 - v. The Barcode Scanner is located in the back panel of the Analyzer.

Warning! Laser Radiation – Do not stare into the beam or view directly with an optical instrument.

The scanning range is approximately 4 – 12 inches from the Scanner. Press and hold the Barcode Scanner symbol. The Barcode Scanner lights up and scanning can be performed. The decoded information from the barcode appears on the Display when the Analyzer identifies the barcode. The information is displayed as long as the Barcode Scanner symbol remains pressed. The symbols on the Display window should only be

touched with the fingertip. To cancel any function, move the fingertip to any area outside of the Symbol and release.

- c. To turn the analyzer off:
 - i. Turn off the Analyzer by pressing the On/Off button. When no procedures have been performed for 30 minutes, the Analyzer will log off the user and then turn itself off.
- d. Only HemoCue Hb 201 microcuvettes can be used with the HemoCue Hb 201 DM.

2. HemoCue Hb 201 Microcuvettes

- a. Microcuvettes are stored at room temperature away from any direct heat source.
- b. Microcuvettes are moisture sensitive. **Always keep the container properly closed.**
- c. Remove required number of microcuvettes just prior to testing.
- d. When removing microcuvettes, slide out one at a time onto a clean flat surface. Do not touch the microcuvette eye.
- e. Unopened containers of microcuvettes may be used until the listed expiration date.
- f. Open containers of microcuvettes are stable for three months (90 days) if they are tightly sealed between uses.
- g. **Always label each opened container with the open date, initials, and the new three-month expiration date.**

3. HemoCue Liquid Quality Control: R&D GLU/HGB Control

- a. Two Levels: **Level 1** control, catalog # GH00LX and **Level 3** control catalog # GH00HX
- b. Order from HemoCue at 1-800-323-1674.
- c. An open vial is stable for 30 days when stored at room temperature, 15 - 30° C.
- d. An open vial is also stable for 30 days when stored in the refrigerator at 2 – 8°C.
- e. **Always write the open date, initials, and new expiration date on the vial.**
- f. Unopened controls are stable if refrigerated at 2-8°C until the expiration date on the vial.
- g. Test liquid quality controls each day of patient use for each HemoCue Hb 201DM and each opened container of microcuvettes.

IV. DAILY MAINTENANCE

Each day of patient testing, perform daily maintenance on each HemoCue Hb 201 DM.

1. Check that the analyzer is turned off. The display should be blank.
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.
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.
4. Clean the cuvette holder with alcohol or mild detergent. It is important that the cuvette holder is completely dry before being replaced.
5. A dirty optronic unit may cause the analyzer to display an error code. To clean the optronic unit, proceed as follows.

- a. Use a swab slightly moistened with either alcohol (without additive) or water to clean the inside of the HemoCue Hb 201 DM. Push the swab into the opening of the cuvette holder. Move from side to side 5 – 10 times. If the swab is stained, repeat with a new swab. No further cleaning is required if the swab remains clean. A HemoCue Cleaner can also be used.
- b. Wait 15 minutes before replacing the cuvette holder and using the analyzer.
6. The cover may be cleaned with alcohol without additives or a mild soap solution.
7. The Scanner glass should be cleaned gently with an alcohol pad.
8. Data Transfer
 - a. Docking:
 - i. The Analyzers should be stored in the docking station when not in use. At a minimum, each analyzer must be docked once every 24 hours, for five minutes, to accomplish downloading and uploading of QC data.
 - ii. The Analyzers should be turned On before docking for data transfer.

V. INTERNAL ELECTRONIC QUALITY CONTROL

1. The HemoCue Hb 201 DM analyzer has an internal electronic “SELF-TEST”.
2. Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer.
3. This test is performed every eighth hour if the analyzer remains switched on. The result of the self-test is stored as an EQC.

VI. LIQUID QUALITY CONTROLS

Each HemoCue Hb 201 DM must be tested with two levels of liquid controls each day of patient testing. In addition, if more than one container of microcuvettes is open you must test liquid controls on each open vial of microcuvettes. Liquid quality controls assure the proper functioning of the entire test system.

1. Put on gloves. Observe Standard Precautions.
2. Warm refrigerated controls at room temperature for a minimum of 15 minutes, preferably for one hour before using.
3. Turn HemoCue Hb 201 DM on:
 - a. Pull the black cuvette holder out to the “LOADING” position.
 - b. Press and hold the On/Off button until the display is activated. The analyzer will automatically perform an internal electronic “SELF-TEST”.
 - c. The analyzer will then ask for the Operator ID. This can be performed by Bar code scanning or manual entry.
 - i. To scan the Operator ID, press and hold the Barcode Scanner symbol. The Barcode scanner lights up and scanning can be performed. When the barcode has been read, the information will appear on the display.
 - ii. To manually enter Operator ID, press either ABC for text mode or 123 for numeric mode depending upon the first character that is to be entered.
 - iii. For Text mode entry. Inputs are made using the Letter boxes. The text mode boxes are clustered with 3 letters per box. To access the third letter i. e. the letter C, quickly press the ABC box three times to move to the letter C. Wait a few seconds to enter the next letter. To toggle between numeric and text press the 123 box.
 - iv. Press the Arrow symbol to correct any incorrect entries.

- v. When all information has been entered, press OK.
 - vi. For Numeric mode entry, press the 123 box, then press the desired numbers.
4. The Analyzer is set for Liquid Quality Control lock out. Two levels of liquid quality control, **Level 1** and **Level 3**, must be performed every 24 hours of patient testing.
 - a. On the Analyzer, press QC.
 - b. For the **Level 1**, press **Level 1**. The analyzer will display “Please Fill and Insert a Cuvette”.
 5. Remove a microcuvette by sliding it out onto a clean surface. Do not touch the optical eye. Reseal container immediately.
 6. Mix control thoroughly. Roll control between the palms for 20 seconds and gently invert it from end to end 10 times. Do not shake or cause it to become foamy.
 - a. Remove the cap and squeeze the vial to expel the hanging drop of control.
 - b. Hold the microcuvette with the pointed end away from you.
 - c. Place the drop of control on a hydrophobic surface. Allow the microcuvette to fill by capillary action. Wipe away any excess control with a Kimwipe before replacing the cap.
 Note: Contents of the control vial should not be allowed to directly contact the HemoCue Hb 201 microcuvette due to possible back transfer of reagent, thus it is not recommended to use a hanging drop from the control vial.
 7. Gently wipe the outside of the microcuvette with a Kimwipe or gauze using a sideways motion. Do not touch the open slit.
 8. Examine the microcuvette for bubbles. Repeat sampling with a new microcuvette if bubbles are present.
 9. Place the filled microcuvette in the cuvette holder.
 10. Push the cuvette holder to the “MEASURING” position.
 11. Enter the Control Lot number. The Control Lot number is the last three digits of the control lot on the open vial. For example **Level 1**, Lot # GH0261, enter 261 as the correct lot number.
 12. Upon completion of QC, the Analyzer will beep and display a numeric result in g/dL as well as Pass or Fail. The result will remain on the display as long as the cuvette holder is in the “MEASURING” position.
 13. If the results are acceptable, press OK. The Analyzer will return to the main menu.
 14. For all failed results, a comment must be entered. Press the Tablet symbol, press Add, then choose a pre-entered comment or free text in a comment. The pre-entered comments are:
 - a. Cleaned Analyzer
 - b. Repeated QC
 - c. Switched Controls
 - d. Procedure Error
 - e. LQC not at Rm Temp
 - f. Operator Error
 15. Pull the black cuvette holder out to the "LOADING" position.
 16. Dispose of microcuvette in a biohazard waste container.
 17. Repeat above procedure for the **Level 3** control.
 18. If control value exceeds the acceptable range, repeat the maintenance and the control.
 19. If repeat controls again fail, take corrective action.
 - a. Check the open date and expiration date on the microcuvette container.
 - b. Check the open date and expiration date of the control.

- c. Follow corrective actions listed in the HemoCue Hb 201 DM Reference Manual, Chapter 12 Troubleshooting.

VII. SPECIMEN REQUIREMENTS

1. Verify patient identification, using two patient identifiers. Sample must be labeled (per Specimen Collection guidelines) if testing is not performed immediately, in the presence of the patient.
2. Volume required: Ten microliters of whole blood.
3. Blood sample may be collected by fingerstick, heelstick or venipuncture.
4. Venipuncture samples can be collected in a vacuum tube with either an EDTA or heparin anticoagulant. Mix immediately by gentle inversion.
5. Unacceptable samples: blood collected in tubes with citrate as the anticoagulant.

VIII. PATIENT TESTING

1. Put on gloves. Observe Standard Precautions.
2. Turn on the HemoCue Hb 201 DM.
3. Enter Operator ID.
4. Run LQC if it has not been performed. Note: if LQC has not been performed, the Microcuvette symbol for patient testing does not appear on the Main Menu screen. Once LQC is performed, Patient Testing can then begin.
5. To run a patient, press the Microcuvette symbol.
6. The Analyzer will display “Please Fill and Insert a Cuvette”
7. Remove a microcuvette by sliding it out onto a clean surface. **Do not touch it. Reseal container immediately.**
8. Obtain patient sample following nursing guidelines.
 - a. Sample obtained by fingerstick:
 - i. Wipe away the first drop of blood.
 - ii. Apply light pressure to the finger until a drop of blood forms. Do not squeeze the finger.
 - iii. Hold the microcuvette with the pointed end away from you.
 - iv. Touch the pointed tip of the microcuvette to the drop of blood.
 - v. Allow the microcuvette to fill by capillary action
 - b. Sample from vacutainer tube:
 - i. Mix tube by gentle inversion 10 times and remove the stopper. Observe standard precautions.
 - ii. Hold the microcuvette with the pointed end away from you.
 - iii. Touch the pointed tip of the microcuvette to the tip of the sample syringe and allow the microcuvette to fill by capillary action.
 - iv. **Vacutainer tube must be labeled with correct patient identification.**
9. Gently wipe the outside of the microcuvette with a Kimwipe or gauze using a sideways motion. **Do not touch the open slit.**
10. Examine the microcuvette for bubbles. If bubbles are present, use a new microcuvette and repeat sampling.
11. Place the filled microcuvette in the black cuvette holder and push the cuvette holder to the "MEASURING" position.
12. During the measurement the screen will read “Please Wait Measuring . . .”.
13. Upon completion, the Analyzer will beep and the patient test results will be displayed in g/dL.

- a. If the results are acceptable, press OK.
 - b. If the operator wishes to enter a comment, press the Tablet symbol. Press Accept or Reject for the current measurement after a comment has been entered.
 - c. If a repeat specimen is necessary, press the Double Microcuvette symbol.
14. Read and record results.
 15. Pull out the black cuvette holder and dispose of the microcuvette in a biohazard waste container.
 16. If the microcuvette is not inserted into the HemoCue Hb 201 DM immediately after sampling, keep it in a horizontal position. Testing must be completed within 10 minutes of sampling.

IX. REPORTABLE RANGE

1. The system is factory calibrated against the hemoglobincyanide method, the international reference method.
2. The Analyzers reportable range is 0-25.6 g/dL.
3. Results above 25.6 g/dL will be displayed an overrange.
4. Values above 23.5 g/dL must be confirmed by the Clinical Laboratory.
5. NORMAL VALUES

Sex	Age	Normal Values
	0-7 days	14.5-22.5 g/dL
	8-14 days	13.5-21.5 g/dL
	2-4 wks	12.5-20.5 g/dL
	1-2 mos	10.0-18.0 g/dL
	2-3 mos	9.0-14.0 g/dL
	3-6 mos	9.5-13.5 g/dL
	6-24 mos	11.0-13.5 g/dL
	2-5 yrs	11.2-13.5 g/dL
	5-8 yrs	11.4-15.5 g/dL
	8-12 yrs	11.6-15.5 g/dL
Male	12-15 yrs	12.3-16.0 g/dL
	15-18 yrs	12.6-17.0 g/dL
	18+ yrs	13.6-17.5 g/dL
Female	12-15 yrs	11.8-15.5 g/dL
	15+ yrs	12.0-15.5 g/dL

References for Normal Values: UCSF Clinical Laboratories Manual

6. HEMOGLOBIN PANIC VALUES
 - a. ≤ 7 g/dL. Repeat the test. Draw a sample and send it stat to Clinical Labs for confirmation.

X. PRECAUTIONS AND LIMITATIONS

1. Air bubbles in the microcuvette will result in erroneously low values. The microcuvette should be inspected for bubbles before testing.
2. The microcuvette should be filled in a continuous process. It should never be topped off after the initial filling.

3. Blood inside the HemoCue Hb 201DM will interfere with hemoglobin measurement.
4. Blood collected in vacutainer tubes with liquid anticoagulant may give erroneous readings due to the effects of dilution.
5. If the HemoCue Hb 201DM displays an error code, refer to the Troubleshooting Guide located in the Reference Manual.
6. R&D GLU/HGB Controls contain human red cells. Use Standard Precaution when handling controls.

X. REFERENCES

1. HemoCue Hb 201DM Analyzer and HemoCue DM Docking Station Reference Manual.
2. HemoCue Hb 201Cuvette Package Insert.