Clinical Laboratory Department POLICY AND PROCEDURE

POLICY NUMBER: 866
VERSION: 3

SUBJECT: Hemoglobin Monitoring: Use of Hemocue Hb201DM Analyzer

PURPOSE:

To provide guidelines for the safe and accurate measurement of hemoglobin values from whole blood. This test can be used as definitive or for screening purposes.

POLICY:

Hemoglobin measurement will be used for general screening, monitoring, and/or treatment of identified patients with diseases, conditions and treatments which can potentially alter hemoglobin levels, per provider order.

Only designated authorized personnel will perform hemoglobin measurement and must demonstrate competency in performing hemoglobin monitoring annually. Competency must be demonstrated to and deemed satisfactory by the Clinical Instructor or designee.

SPECIMEN:

Patient Preparation:

Capillary blood can be obtained from piercing the fingertip using a safety single-use lancing device. The puncture site should be cleaned with soap and water, and then thoroughly dried before obtaining the sample.

Type:

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

EQUIPMENT AND MATERIALS:

Equipment:

1. HemoCue Hb 201 DM Photometer.

2. HemoCue Hb 201 DM Cuvettes.
3. Safety single-use lancing device.

Materials:

1. Gloves.
2. 2x2 Gauze pads.
3. Glass slides.
4. Bandages.
5. Hemoglobin Control Solutions (2 levels).

Reagent Storage Requirements:

1. The Microcuvettes are to be stored at room temperature (15-30°C or 59-86°F). DO NOT REFRIGERATE.
2. The expiration date for the Microcuvettes is three months from the date opened or the manufacturer's expiration date, whichever comes first.
3. Protect the Microcuvettes from moisture and close package immediately after removing cuvettes.
4. Store the Hemoglobin Control solutions in the refrigerator (2-8□ C or 35-46° F). DO NOT FREEZE. Remove the controls from the refrigerator and allow warming to room temperature for 2-3 minutes before testing.
5. The open date and date of expiration along with the user's initials are to be recorded on the bottles of open control solution and Microcuvettes.
6. Once opened, the control solutions are stable for 30 days. Discard any unused portion after 30 days.
7. The operating temperature for the HemoCue Photometer is to be 15-30° C or 59-86°F. Allow the Analyzer and Docking Station to reach this temperature before use. They should not be operated in high (>90%, non-condensing) humidity.

PROCEDURE:

A. ANALYZER OVERVIEW:

The Analyzer is started when the On/Off button is pressed. The screen images will be visible on the display. All navigation and information handling is performed by pressing the appropriate touch buttons directly on the Display. To perform a measurement, the Cuvette is filled with sample material and placed in the Cuvette holder. The Cuvette holder is then inserted into the Analyzer.

B. POWER SOURCE:

The Analyzer can be powered either by the rechargeable battery or by a standard electrical outlet via the AC Adapter. The rechargeable battery is located in a battery compartment on the bottom of the Analyzer. Recharge the battery by connecting the AC adapter to the Analyzer or by placing the Analyzer in the Docking Station. The battery lasts for several years. It should be replaced when it fails to retain its charge for an acceptable period.

When no procedures have been performed within the time predefined in the settings, the Analyzer will switch to power save mode. If the Analyzer is powered via the AC adapter, the user will be logged off, the image on the display will disappear, but the power will remain on. Touch the Display to reactivate it. If the Analyzer is powered via the battery, the user will be logged off and the Analyzer will be switched off. Press the

On/Off button to reactivate it. Do not turn off the Analyzer in the middle of a procedure. Data may be lost.

C. DOCKING STATION:
A steady green light from the LED indicates that the Docking Station is receiving power and that the battery is fully charged. A flashing green light from the LED indicates that the battery in the docked Analyzer is charging and communicating. A steady red light from the LED indicates an internal communication error within the Docking Station. A flashing red light from the LED indicates an external communication error.

D. OPERATING THE DISPLAY:
The buttons appearing on the display activate the specific functions symbolized by the image on the button. The buttons should only be pressed using the fingertip. Sharp-edged objects can damage the display. When a button is pressed, it will appear highlighted as long as it is pressed. When the button is released, the function indicated by the button is activated. To change a function, keep pressing while moving the fingertip over to another button. The original button will cease to appear highlighted and the new button will appear highlighted. To cancel a function, keep pressing while moving the fingertip over to an area without buttons, then no button will appear highlighted, and when the finger is released, no action will be done. The Main Menu is displayed as the Startup Image for all tests, setting procedures, etc. See attached sheet for Display buttons and symbols. The Help button (?) may be used to display information about other buttons. Inputs to the Analyzer such as operator ID, patient ID, etc., can be made via the display. The display can be set to two different modes, text mode for entering letters and numeric mode for entering digits. After all information has been entered, press the Confirm button (OK).

E. QUALITY CONTROL:
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. This test is performed every 8th hour if the Analyzer is left turned on.

Hemoglobin Control Solutions:

1. Used to check the quality control of the total system, i.e. photometer and Microcuvette (Normal and Low Abnormal Control Solutions).
2. Quality Control is required to be performed each day the clinic is open to patients.
3. If values fall outside the expected range: NO PATIENT TESTING WILL BE DONE until remedial action is taken.
    a. If the situation cannot be remedied, send the unit to the laboratory for a replacement.
    b. Check for procedural errors:
        - The cuvettes are too old or damaged, improper storage.
        - The optical eye of the cuvette is contaminated.
        - The control solution is not mixed well and/or not at room temperature.
        - Air bubbles are present in the cuvette.
        - The optronic unit is dirty.

- The control is not suitable for the HemoCue system.

F. QUALITY CONTROL PROCEDURE:

1. Remove the control solutions from the refrigerator and allow them to sit at room temperature for 2-3 minutes before testing.
2. Check expiration dates of solutions (once opened they are stable for 30 days, or the manufacturer's expiration date –whichever comes first).
3. The QC Reminder icon will be displayed in the Main menu to warn of an impending QC lockout. If the QC is not performed within the pre-defined reminder time, the Analyzer will perform a lockout. To unlock the Analyzer, the required QC measurements must be performed and approved. Patient Tests cannot be performed during a lockout.
4. In the Main Menu press the QC Test button. In the next display, choose the required QC level.
5. Take out two Microcuvettes and reseal the container immediately after checking the expiration date (once opened, stable for 3 months).
6. Wash hands and don gloves.
7. Mix the "Normal" control solution well and place a drop on a piece of scotch tape to facilitate filling of the Cuvette.
8. Holding the Cuvette at the rear with two finders, bring the filling edge into contact with the specimen.
9. When filled, wipe off the excess solution from the sides of the outside of the Microcuvette with a lint-free tissue (gauze pad).
10. Place the filled Cuvette in the open Cuvette holder and gently insert it into the measuring position
11. Enter or scan the required information, via the Text mode and Numeric mode buttons. If a Control lot number has not been previously stored in the Analyzer and/or has expired, the following text will be displayed: "Invalid control Lot."
12. The Analyzer will automatically start the measuring procedure.
13. The result will be displayed when all required information has been entered and the measurement has been completed.
    - For a result within the Approved area, the Qualitative Test Result will indicate, "Pass."
    - For a result within the Fail area, the Qualitative Test Result will indicate, "Fail."
    - To avoid or unlock a QC lockout, The QualitativeTest Result must indicate, "Pass."
14. All "Failed" results MUST have a comment added. 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. A dotted Comment book indicates that comments have been added to the result.
15. Press the Confirm button to store the information.
16. The Main Menu will be displayed. Pull the holder out and discard the cuvette in a sharps container.
17. Repeat steps 6 through 11 using the Low Abnormal Control solution.
18. Remove gloves and wash hands.
19. Turn the meter off if it will not be used for several hours or return it to the docking station and leave it on.

G. PATIENT TEST:

1. Must have a provider's order (either in ORCHID or as a written protocol order).
2. Identify patient with at least 2 acceptable identifiers.
3. Follow infection control guidelines.
4. Explain the procedure to the patient.
5. Have the patient wash his/her hands with soap and warm water and dry hands thoroughly with a lint-free wipe
6. Take out only as many Microcuvettes as needed (check expiration date) and reseal the package immediately.
7. Wash hands and put on clean gloves (and any other protective equipment that may be needed).
8. While applying light pressure toward the fingertip, puncture the finger using the lancet. Wipe away the first 1-2 drops of blood with a lint free wipe.
9. Dispose of the lancing device in a sharps container.
10. Re-apply light pressure towards the fingertip until another drop of blood appears. When the drop is large enough, and holding the Cuvette with two fingers at the rear, bring the Cuvette filling edge into contact with the specimen and allow the Cuvette to fill by capillary action in one continuous process. Avoid overfilling or air bubbles. Never refill. If any air bubbles are present, fill a new Cuvette. Small bubbles around the edge can be ignored.
11. Apply a gauze pad or cotton ball over the puncture site with light pressure until the bleeding stops. 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.
12. Wipe off excess blood on the outside of the cuvette tip with a lint-free tissue or gauze pad being careful not to touch the open end of the Cuvette.
13. In the Main Menu, press the Patient Test button.
14. Place the filled Cuvette into the Cuvette holder and push the holder to the Measuring position. The filled Cuvette should be processed immediately and, at the latest, 10 minutes after filling.
15. Scan in the required information. You must always scan the FIN number. NEVER enter the number manually
16. The result will be displayed when all the required information has been entered and the measurement has been completed (15-60 seconds).
17. <u>All critical values must have a comment added</u>. 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. A dotted Comment book on the display 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 same patient.
18. Press the Confirm button to store the information. The Main Menu will then be displayed. The result will remain on the display until the Confirm button has been pressed.
19. Pull the holder out and discard the Cuvette in the bio hazardous Sharps container.

20. Dock the meter. Once the meter is docked and it says “data transfer”, and the above steps were followed, the results will chart in ORCHID. NEVER enter the hemoglobin result manually into Cerner. If this is done, TWO results will post to ORCHID.
21. Remove gloves and wash hands.
22. Turn the meter off if it will not be used for several hours, or dock it and keep it turned on.
23. Notify the provider of all results.

CRITICAL VALUE:

All critical values are programmed into the HemoCue. For any critical result obtained, repeat the test. Any repeated results that fall above or below the limits of the critical range are considered critical values and the patient’s physician/caregiver must be notified immediately. At the physician’s discretion or request, a venous specimen may be collected and sent to the laboratory for confirmation.

H. MAINTENANCE/CLEANING:

1. The cuvette holder shall be cleaned after each day of use. To clean the Cuvette holder, pull the Cuvette holder out to the Loading position. Then carefully press the small catch positioned in the upper right corner of the Cuvette holder. While pressing the catch, carefully rotate the Cuvette holder sideways as far as possible to the left. Remove the Cuvette holder from the Analyzer. Clean the Cuvette holder with alcohol or a mild soap and water solution. It is important that the Cuvette holder is completely dry before reinserting it into the Analyzer.
2. A dirty optronic unit may cause the Analyzer to display an error code, and cleaning of the optronic unit shall only be done periodically as needed by the POCT coordinator or designee.
3. If the display window gets dirty, it can be cleaned with an alcohol pad (without additives).
4. The analyzer’s outer case must be cleaned after each patient test. To clean the analyzer outer case and/or the docking station, make sure that the analyzer is turned off. The display should be blank. The outer case on the analyzer and the docking station may be cleaned with alcohol or a mild soap solution or a facility approved disinfectant.
5. The counter top at the workstation where the analyzer is used shall be cleaned after each day of use with the appropriate cleaning solution.

TROUBLESHOOTING:

Symptom	Explanation	Action.
The photometer shows An error code	May be an occasional fault.	1. Turn off the Analyzer and switch it on again after 30 seconds. Take a new cuvette and repeat the measurement. If the problem continues, see specific error code below.
E00	No stable endpoint found within the time range. 1. The cuvette is faulty. 2. Circuit board is out of order.	la. Check expiration date for the cuvettes. - lb. Take a new cuvette and repeat the measurement. 2. The Analyzer needs service. Call the lab.
E01-E05	Fault in the optics or electronics	1. Turn off the Analyzer and call the lab to clean the optronic unit. 2. The Analyzer needs service. Call the lab.
E06	Unstable blank value. The Analyzer might be cold.	1.Turn off the Analyzer and allow it to reach room temperature. If the problem continues, The Analyzer needs service, call the lab.
E08	The absorbance is too high. Light blocking item in the Cuvette holder.	1. Check that the Analyzer and Cuvettes are used according to the Instructions for use. 2. The Analyzer needs service. Call the lab.

E11	Hardware Error	1. The Analyzer needs service. Call the lab.
E17	Internal Error	1. The Analyzer needs service. Call the lab.
E23	Data Error Real Time Clock or Real Time Clock backup battery has been drained.	1. The backup battery needs to be replaced. Contact the Laboratory.
E25	Analyzer not calibrated.	1. The Analyzer needs service. Call Technical Service.
E26	The Patient test memory is full. Nor more patient test data can be saved.	1. Call Laboratory.
E27	The QC memory is full. No more QC data can be saved.	1. Call Laboratory.
E28	The Analyzer log memory is full. No more Error Codes and Log Notes can be saved.	1. Call Laboratory.
E29	The electronic selftest failed, The communication selftest failed, The Analyzer may not work properly when connected to a docking station. This is stored as a failed Electronic QC test (EQC) in the Analyzer Log book.	1. The Analyzer needs service. Call the lab.
E30	The electronic selftest failed. The optical selftest failed. The Analyzer may not work properly when measuring. This is stored as a failed Electronic QC Test (EQC) in the Analyzer Log book.	1. Turn off the Analyzer and call the lab to clean the optonic unit. 2. The Analyzer needs service. Call the lab.
E31	Communication Error	1. Contact the Laboratory.
Overrange	Measured value exceeds 25.6 g/dL	

REFERENCES:

HemoCue Hb 201 DM Analyzer Operating Manual, Hemocue AB, Sweden.

High Desert Health System Laboratory Policy/Procedure Manual, 2006

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