HemoCue® Hb 201+ Procedure Template

PURPOSE

The HemoCue Hb 201+ System is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, HemoCue Hb 201+, and specially designed HemoCue Hb 201 Microcuvettes.

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., for prospective blood donors and in the assessment of womens’ and childrens’ health.

PRINCIPLE

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. Measurements are taken at 570nm and 880nm; the latter to correct for turbidity.

SAMPLE COLLECTION AND PREPARATION

No special patient preparation is required. Capillary (e.g., fingerstick), venous or arterial blood may be used. Appropriate anticoagulants in solid form (e.g., EDTA, heparin or heparin/fluoride) may be used. Mix all anticoagulated samples thoroughly on a mechanical mixer for at least two minutes or invert the tube 8-10 times by hand. Alternatively, follow the local recommendations. Hemoglobin remains unchanged for days provided that the blood 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 up to room temperature before mixing.

EQUIPMENT, REAGENTS, AND SUPPLIES

HemoCue Hb 201+ Analyzer
HemoCue Hb 201 Microcuvettes (store at room temperature)
Liquid controls (optional - store according to manufacturer’s specifications)
Blood lancets, needles, syringes, blood-collection tubes
Gloves
Disinfecting solution
Lint-free tissue such as Celltork or gauze
Hydrophobic material such as Parafilm®
PROCEDURE

Gloves should be worn at all times during the testing procedure and all appropriate laboratory safety guidelines should be followed.

A. Start Up Procedure

1. Pull the cuvette holder out to the loading position. Press and hold the left button until the display is activated (all symbols appear on the display).
2. The display shows the version number of the program, after which it will show “2” and “Hb”. During this time the analyzer will automatically verify the performance of the optronic unit by performing an automatic SELFTEST.
3. After 10 seconds, the display will show 3 flashing dashes and the HemoCue symbol. This indicates that the HemoCue Hb 201+ analyzer has passed the SELFTEST and is ready for use. If the SELFTEST fails, an error code will be displayed.

B. Quality Control

SELFTEST
The HemoCue Hb 201+ 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 second hour if the analyzer remains switched on.

Liquid Quality Control
If use of liquid control material is required by local or other regulations, contact HemoCue, Inc. for control information. Follow the manufacturer’s procedure for storage and handling of the control material.

1. The analyzer should be in the “ready” mode prior to filling the cuvette.
2. Dispense a drop of control onto a hydrophobic surface and follow Steps 9-16 of the Capillary Testing – Finger section. Note: Some control products require a “waiting period” prior to inserting the cuvette into the analyzer for measurement. Follow the directions in the package insert for the control product.
3. Record the results on a quality control log.
4. If the results do not fall within the established range, follow local policy for failed quality control prior to performing any patient testing.

C. Patient and Specimen Testing

Capillary Testing - Finger
1. To perform a test using capillary blood, the cuvette holder should be in its loading position. The display will show three flashing dashes and the HemoCue symbol.
2. The hand should be warm and relaxed. Heating the hand with warm water, or by some other means, is a good idea to increase the blood circulation. The patient’s fingers should be straight but not tense, to avoid stasis. It is best to use the middle or ring finger
for sampling, but fingers with rings should be avoided due to the chance of decreased circulation.

3. Remove a cuvette from the vial or the individually wrapped package. Recap the vial immediately.
4. Clean the finger with alcohol or a suitable disinfectant. Then wipe dry with a clean, dry lint-free wipe or allow it to air dry completely.
5. Using gentle pressure, rock your thumb from the top of the patient’s distal knuckle to the fingertip. This stimulates the blood flow towards the sampling point.
6. Press the lancet firmly against the finger prior to activating the lancet to aid in obtaining a good sample.
7. While maintaining gentle pressure on the tip of the finger, perform the stick off-center on the fingertip. Discard the lancet in an approved container.
8. Using a dry gauze or other lint-free tissue, wipe away the first two or three large drops of blood, applying light pressure as needed again until another drop of blood appears. This stimulates blood flow and lessens the likelihood of a dilutional effect by interstitial fluid. Avoid “milking of the finger”.
9. Make sure that the drop of blood is big enough to fill the cuvette completely. Hold the cuvette opposite the filling end and introduce the cuvette tip into the middle of the drop of blood. Fill the cuvette in one continuous process. Do not refill a partially filled cuvette.
10. 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.
11. Visually inspect the cuvette for air bubbles in the optical eye. If bubbles are present in the optical eye, the cuvette should be discarded and a new sample taken for analysis. (Small air bubbles around the edge do not influence the result).
12. The filled cuvette should be analyzed immediately, or at the latest, 10 minutes after it has been filled. Place the filled cuvette into the cuvette holder and gently slide the holder into the measuring position.
13. During the measurement, “2” and three fixed dashes will be shown on the display.
14. The result will be displayed within 15 to 60 seconds and will remain on the display as long as the cuvette holder is in the measuring position. When operating on battery power, the analyzer will automatically turn off after approximately five minutes.
15. Pull the cuvette holder out to the loading position. Remove the cuvette and discard it in an appropriate biohazard container, following local procedures for disposal.
16. When the display shows three flashing dashes and the HemoCue symbol, the analyzer is ready for the next measurement.

**Venous or Arterial Specimen from Vacuum Tubes**

1. Obtain a specimen according to established procedure. A fresh, well-mixed anticoagulated blood sample is to be used. Samples stored at 2-8°C (35-46°F) may be used but must be allowed to come to room temperature prior to testing.
2. Mix the sample on a mechanical mixer for at least 2 minutes or gently invert by hand 8 to 10 times.
3. Dispense a drop of blood onto a hydrophobic surface.

**Venous or Arterial Specimen from Syringes**
NOTE: It is very important to test the sample immediately to avoid potentially erroneous results due to coagulation or separation of the specimen.

1. Obtain a specimen according to established procedure.
2. Mix the syringe according to local procedure.
3. Dispense a drop of blood onto a hydrophobic surface.

D. Maintenance
The analyzer has no serviceable parts.

1. Cuvette Holder
   • The cuvette holder should be cleaned after each day of use.
     a. Check that the analyzer is turned off (the display should be blank).
     b. Pull the cuvette holder out to the loading position. Using a pointed object or your fingertip, carefully press the small catch in the upper right hand corner of the cuvette holder.
     c. While pressing the catch, carefully rotate the cuvette holder to the left as far as possible.
     d. Clean the cuvette holder with alcohol or a mild detergent and allow to dry completely before replacing it in the analyzer.

2. Analyzer
   • The exterior of the photometer may be cleaned as necessary with alcohol or a mild soap solution.

3. Optronic Unit
   • The optronic unit should be cleaned as directed in the Troubleshooting Guide of the HemoCue Hb 201+ Operating Manual. See the instructions in the Maintenance section of the Operating Manual or call HemoCue, Inc. Technical Support.
E. Procedural Notes

1. Microcuvettes are stored at room temperature, away from any direct heat source. The vial should be kept tightly capped and cuvettes should be removed as needed for testing just prior to use. Unopened cuvettes have a shelf life of two (2) years from the date of manufacture. The expiration date is printed on each vial. Vials of cuvettes that have been opened are stable for three (3) months if the cap is kept on tightly between uses and stored correctly. When opening a new vial, label with the date opened. “The individually packed microcuvettes are stable until the expiration date printed on each package”.

2. The HemoCue Hb 201+ analyzer corrects for turbidity in specimens, and therefore might produce lower results than those expected for other hemoglobin instruments that do not have this correction feature. Therefore, if required, only controls that are assayed for the HemoCue Hb 201+ system should be used.

3. Results above 25.6g/dL will be displayed as HHH. Refer to the Troubleshooting Guide in the Operating Manual for interpretations of other error codes.

F. Limitations of the Procedure

Values above 23.5 g/dL must be confirmed using a suitable laboratory method. Sulfhemoglobin is not measured with this method. Carboxyhemoglobin levels up to 10% do not interfere with the system.

G. Normal Values

Normal values should be established for the patient population being tested. Normal values used by local hospitals, etc. may be acceptable for use.

H. Problem Solving

Refer to the “Troubleshooting” section of the Operating Manual if problems arise. If problems persist, contact HemoCue, Inc. Technical Support at 1-800-426-7256 for more detailed instruction.

I. References

HemoCue Hb 201+ Operating Manual (050523)
HemoCue Hb 201 Microcuvette Package Insert (050523)

For additional information please contact:
HemoCue, Inc.
Attention: Technical Support
40 Empire Drive
Lake Forest, CA  92630
800-426-7256
**HemoCue® Hb 201⁺ System Maintenance Log**

Analyzer Serial Number ______________________

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<th>CORRECTIVE ACTION</th>
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# HemoCue® Hb 201+ Quality Control Log

**Begin a new log with each new lot number of microcuvettes**

**Analyzer Serial Number:**

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<td>± g/dL</td>
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