



HealthPartners/GHI

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| HemoCue Hemoglobin (Nokomis and Highland Park Clinics Only) | | Attachments <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
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| <u>APPROVAL(S)</u> Laboratory Medical Director | | |

HemoCue Hgb
Clinic Lab Procedure (Pages 1-5)
Computer Test (Page 6 -7)

I. PURPOSE/PRINCIPLE

This procedure provides direction for performing a hemoglobin test using the HemoCue point-of-care meter.

The HemoCue Hemoglobin system is based on an optical measuring microcuvette of a small volume and a short light path. The microcuvette cavity contains reagents deposited on its inner walls. The blood sample is drawn into the cavity by capillary action and is mixed spontaneously with the reagents.

The microcuvette is then placed in a HemoCue Hb 201+ analyzer in which the transmittance is measured and the hemoglobin level calculated. This technique makes it possible to sample the blood, mix and chemically react it with the reagents in the same microcuvette that is used for measurement. The microcuvette is made of polystyrene plastic and comprises a body having a cavity with a volume of 10uL. The distance between the walls of the optical window is 0.130 mm, which permits photometric determination of the hemoglobin in undiluted blood.

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous state to the ferric state to form methemoglobin, which then combines with azide to form azidemethemoglobin.

II. POLICY

Laboratory Staff will follow the approved techniques outlined in this procedure.

HealthPartners family of care uses single-use needle and devices for all phlebotomy and blood collection procedures. Should it be necessary to re-stick a patient, a new, single-use needle or device will be used.

HealthPartners family of care will clean the outside of a POCT meter with an approved disinfectant wipe (i.e., Sanicloth AF) after each patient test for meters that come into direct contact with patients in accordance to HPMG policy and CDC requirements.

Specimen:

Capillary or venous blood collected in the appropriate anticoagulant (e.g. EDTA, Heparin or heparin/fluoride) may be used. Mix all samples thoroughly on a mechanical mixer or at least two minutes or invert the tube 10-20 times by hand. The specimen may be stored in the refrigerator (2°-8° C) for up to 24 hours. If the specimen has been stored in the refrigerator, the blood should be warmed to room temperature before mixing.

Reagents/Materials

- HemoCue Hb 201+ analyzer
- HemoCue Hb Microcuvettes
 - Microcuvettes are good until the expiration date which is printed on each package.
 - Store the microcuvettes at room temperature (15°-30° C).
 - DO NOT REFRIGERATE.
 - Hgb Microcuvettes are wrapped individually. Do not open prior to testing.
- Liquid controls: R&D system Hgb Controls

Calibration:

No additional calibration is necessary. The HemoCue Hb 201+ analyzer has an internal electronic "SELFTTEST". 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.

Quality Control:

R&D Hgb Control:

- Run 3 levels of controls (Low, Normal, High) each day of testing to check the total system.
- Store control vials at 2°- 8° C. Unopened vials are stable until the expiration date.
- After opening the vial, it is stable for 30 days. Document opened date and new expiration date on the vials.
- Control should be similar in appearance to fresh whole blood. In unmixed vials the supernatant may appear pink; this is normal and does not indicate deterioration. Dark red supernatant fluid, discoloration of the product or unacceptable results may indicate deterioration. Do not use the product if deterioration is suspected.
- Record the results on the HemoCue Hemoglobin Control log sheet.

Running controls:

1. Remove control vials from the refrigerator and allow vials to warm at room temperature (15°-30° C) for 15 minutes before mixing.
2. To mix, hold a vial horizontally between palms of the hands. Do not pre-mix on a mechanical mixer.
 - a. Roll the vial back and forth for 20-30 seconds; occasionally invert the vial. Mix vigorously but do not shake.
 - b. Continue to mix in this manner until the red cells are completely suspended. Vials stored for a long time may require extra mixing.
 - c. Gently invert the vial 8-10 times immediately before sampling.
3. Remove cap from vial. Do not sample directly from vial. Dispense a drop of control onto parafilm, glass slide or other appropriate material.

4. Wipe the rim and cap of the control vial with a clean tissue and replace the cap.
5. Touch the tip of the microcuvette to the drop of control material. Capillary action will draw the control into the microcuvette. The cuvette should be filled in one continuous motion, with no air bubbles.
6. Wipe off the excess control material on the outside of the microcuvette tip, taking care not to touch the opening.
7. Pull out the microcuvette holder to the loading position. This point, which should not be exceeded, is easily established by paying attention to a distinct stop. The display shows the letters "Hb".
8. After approximately two seconds the indication "READY" appears on the display together with three flashing dashes. The analyzer is ready for measurement. Place the microcuvette into the holder and push it into the measuring position.
9. The display now shows "MEASURING" and three fixed dashes. An hour glass symbol indicates the analyzer is measuring.
10. After approximately 15-60 seconds the result will be displayed.
11. Record the result on the HemoCue Hgb control log.

III. PROCEDURE

1. Pull the microcuvette holder out to its loading position. Press and hold the on/off button until the display is activated. Pull out the holder to insertion position.
2. The display should show the version number of the program followed by an hourglass and "Hb". During this time the analyzer will automatically verify the performance of the optronic unit. After approximately 10 seconds the display should show three blinking dashes with the HemoCue symbol. This indicates that the analyzer is ready for use.
3. Unwrap a Hgb microcuvette. Hold the microcuvette by the rear winged end. Avoid touching the measurement area.
4. **Capillary Samples: (If venous or arterial, proceed to step 5)**
 - a. The hand should be warm and relaxed. It is a good idea to heat cold hands in warm water before sampling. This increases the blood circulation. The patient's finger should be straight but not tense.
 - b. For best results, use the middle finger or the ring finger for sampling. Avoid fingers with rings for sampling. Clean the puncture site with alcohol and allow it to dry.
 - c. Using your thumb, lightly press the finger from the top of the knuckle to the tip. This stimulates the blood flow towards the sampling point. With the thumbs gentle pressure at the tip of the finger, prick at the side of the fingertip. Not only is the blood flow at its best at this point, it also causes the least pain.
 - d. Wipe away the first drop of blood. This stimulates the blood flow. If necessary, apply light pressure again until another drop of blood appears. Avoid "milking".
 - e. Fill an EDTA microtainer to the minimum mark. Mix appropriately.
 - f. Once mixed, use a transfer pipette to place a blood drop on a piece of parafilm or slide.
 - g. Fill the microcuvette in one continuous process. It should never be topped up after the first filling. Make sure there are no bubbles.
 - h. Wipe off the excess blood on the outside of the microcuvette tip. Make sure that no blood is drawn out of the microcuvette.
 - i. Proceed to step 6.
5. **Venous or arterial blood from tube: (If capillary, refer to step 4)**
 - a. Obtain a venous or arterial blood sample in a tube following the appropriate specimen collection procedure.
 - b. Make sure the specimen is well mixed, at room temperature and less than 24 hours old.
 - c. Using a transfer pipette, place one drop of blood onto a hydrophobic surface such as parafilm or a glass slide.
 - d. Introduce the microcuvette tip into the middle of the drop in such a way that the whole microcuvette is filled in one step. It should never be topped up after the first filling. Make sure there are no bubbles.

NOTE: 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.

6. The filled microcuvette should be visually inspected for air bubbles.
7. Place the filled microcuvette into the microcuvette holder immediately and push it into measuring position. The filled microcuvette should be analyzed immediately and at the latest, 10 minutes after it has been filled. Filled microcuvettes are to be kept lying down.
8. After approximately 15-60 seconds the result is displayed. If "ERROR" code appears, look up the appropriate code on page 30 of the "Trouble Shooting Guide" of the HemoCue Blood Hb 201+ Operating Manual.
9. Record the results on the log sheet.
10. Remove the microcuvette and dispose of properly.

NOTE: If, for whatever reason, the meter is brought to the patient's side for testing, the outside of the meter must be cleaned with an approved disinfectant wipe (i.e., Sanicloth AF) before testing the next patient. Allow the meter to dry before testing. Do not allow moisture into the microcuvette holder area.

Comments/Notes:

1. Linearity Range is 0-25.6 g/dl.
2. Values of <7.0 g/dl or > 19.0 g/dl must be repeated to verify result. If results do not repeat, the sample must be sent to Central lab for verification. Preliminary results may be given.
3. Results that are flagged with delta check failures must be repeated. Attach -pckd to the test.
4. Low values will be indicated by LLL and high values as HHH. Samples exceeding the linearity must be sent to Central lab for testing. Preliminary results may be given. Follow computer entry procedure on page 6.
5. Operating temperature 18-30°C
6. Operating humidity \leq 90%
7. Mixing blood for too long a period can produce increased oxygen pressure and viscosity that may give falsely high readings.
8. 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.
9. Gloves are to be worn during the collection of the specimen and processing of the test.
10. Contents of the control vial should not be allowed to directly contact the HemoCue microcuvette due to possible back transfer of reagent.
11. For Technical Service on the instrument, call 1-800-426-7256.
12. For Technical Service on the R&D Hgb Controls, call 1-800-523-3395
13. Document all trouble shooting, including trouble shooting of function checks and out of range controls on the QC logsheet.

IV: MAINTENANCE

Daily:

1. Turn off the analyzer.
2. Pull the microcuvette holder out to the loading position. Use a pointed object, such as an applicator stick to carefully press the small catch positioned in the upper right corner of the microcuvette holder.
3. While pressing the catch, carefully rotate the microcuvette holder towards the left as far as possible.
4. Carefully pull the microcuvette holder forward and away from the analyzer.
5. Clean the microcuvette holder with a cotton tipped applicator moistened with alcohol. Set it aside to dry.
6. While the microcuvette holder is drying, push an alcohol-moistened cotton-tipped applicator into the opening of the microcuvette holder. Move the applicator in and out 5-10 times to remove any material. If the swab is stained, repeat with a new swab until the swab comes out unstained.
7. Wait 15 minutes for the alcohol to dry before replacing the microcuvette holder into the analyzer.
8. Run all three levels of controls before performing patient tests.
9. Record the cleaning on the maintenance log.

As needed:

1. The cover of the HemoCue may be cleaned with an approved disinfectant wipe (i.e., Sanicloth AF) should the outside of the meter become dirty.

REPORTING RESULTS

Refer to the Computer Entry section of this procedure

REFERENCES

HemoCue Hb 201+ Operating Manual.
HemoCue Hb 201 Microcuvettes Package Insert
R&D Systems Inc. Glu/Hgb Control package insert, 1999, Rev 12/02.

RELATED DOCUMENTS

APPENDIXES

AUTHOR/REVIEWER(S)

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IV. DEFINITIONS

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

VII. OTHER RESOURCES

VIII. ENDORSEMENT

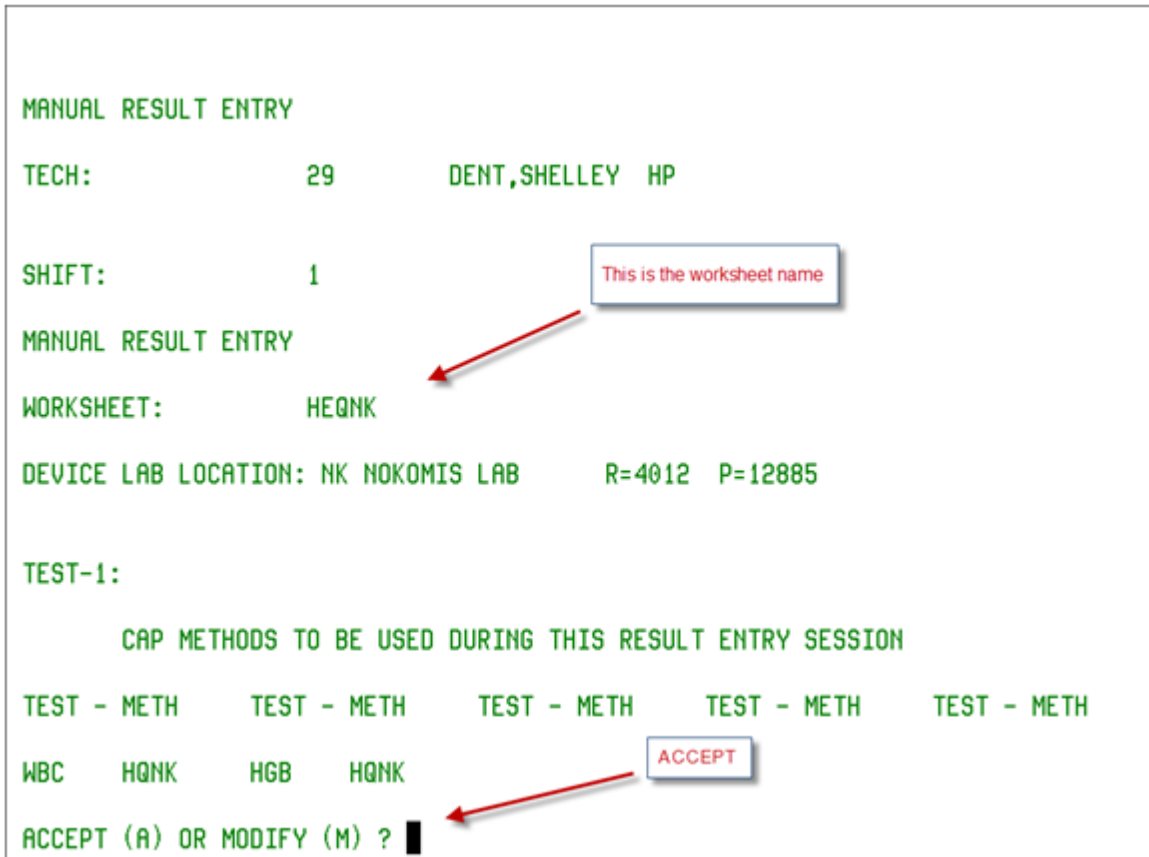
Laboratory Administration

Computer Order and Result Entry

MANUAL RESULT ENTRY

Function: MEM

```
MANUAL RESULT ENTRY
TECH:          29          DENT,SHELLEY HP
SHIFT:         1
MANUAL RESULT ENTRY
WORKSHEET:     HEQNK
DEVICE LAB LOCATION: NK NOKOMIS LAB      R=4012 P=12885
TEST-1:
      CAP METHODS TO BE USED DURING THIS RESULT ENTRY SESSION
TEST - METH    TEST - METH    TEST - METH    TEST - METH    TEST - METH
WBC   HQNK    HGB   HQNK
ACCEPT (A) OR MODIFY (M) ? █
```



Enter to get to Accession number

Enter Accession number of specimen to be resulted

| <u>CODE</u> | <u>NAME</u> | <u>RESPONSE</u> |
|-------------|-------------|---|
| HGB | Hemoglobin | Enter the number directly to one decimal point, ie; 14.2 Append -pckd (all parameters checked) if guidelines indicated specimen should be repeated to verify result |

Hematology Preliminary Results
(Clinic prelim results – final testing at Central Lab)
Order code: HEDP-W

Reporting of Hematology Preliminary Results:

Preliminary reports should be given only when the provider needs a result, but a final result cannot be reported at the clinic. Preliminary results must be documented in the computer since the provider may be providing treatment based on these results.

If the Hgb result of <7.0 or >19.0 does not repeat or the specimen exceeds the linearity limits (LLL or HHH), it **may** be appropriate to give the provider a preliminary result. Call a lab technical consultant if you are unsure as to whether a preliminary result should be given out.

Order the test code HEDP (Hematology Preliminary) and result on worksheet HCON.

Pack specimen tube and a copy of the patient worksheet with the patient result highlighted, in ziplock bag, track and send to Central lab.

ORDERING:

Order only if provider insists on a result before the final comes back from Central Lab. Do not result the Hgb so that Central lab may do so.

RESULTING:

WORKSHEET:

Function MEM, worksheet HCON

RESPONSE:

| <u>Code</u> | <u>Name</u> | <u>Response</u> |
|-------------|--|---|
| HEDFP | Prelim Results | Free text results. Examples ;Hgb > 25.6; exceeds linearity ;Hgb <7.0, unable to verify, sent to Central lab |
| HCALL | Result called to | Free text who received the results. Enter first and last names, date and time. Example; HGB given to Jane Smith, RI OB,12N,030104 |
| HEDP2 | Will be automatically answered with VTF: | “Verification to Follow”. |

Author/Reviewer(s)

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