



HealthPartners/GHI

HemoCue WBC (Cottage Grove, Eagan, Highland, Nokomis, St. Paul)	Attachments <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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<u>APPROVAL(S)</u> Laboratory Medical Director	

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

I. PURPOSE/PRINCIPLE

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

The HemoCue WBC system is used for the quantitative determination of white blood cell count in whole blood from capillary or venous samples. The system consists of an analyzer together with microcuvettes. The microcuvette serves as a sample container and a reaction chamber. The microcuvette is for single-use only. A blood sample of approximately 10 ul is drawn into the testing cavity by capillary action. A hemolyzing agent lyses the red cells in the microcuvette and a staining agent colors the white cells. The microcuvette is placed in the analyzer where an image is taken of the stained white cells and the number counted by image analysis. The result is obtained in 3 minutes. The system was designed and developed to establish agreement with manual light microscopy method for white blood cell counts.

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 WBC analyzer
- HemoCue WBC Microcuvettes
 - Unopened canisters of Microcuvettes are good until the expiration date on the canister.
 - Store the microcuvettes at room temperature (15°-30° C).
 - DO NOT REFRIGERATE.
 - Once the canister seal is broken, the microcuvettes are stable for three months.
 - **Write the open date and new expiration date on the outside of the canister.**
 - Always keep the canister properly closed.
- Liquid controls: R&D system WBC Controls

Calibration:

No additional calibration is necessary. The HemoCue WBC analyzer has an internal electronic "SELFTEST". Every time the analyzer is turned on, it will automatically verify measurement performance. Another part of the self-test is performed for each measurement and the sample itself. The operator's ability to handle the microcuvette and apply the sample correctly is also included in these "self tests".

Calibration verification:

Calibration must be verified every 6 months by testing samples of known value that cover the validated linearity range. Three samples tested by another method (Clinic or Central lab hematology instrumentation) with the approximate values of 2.0, 10.0 and 20.0 k/uL should be tested on each HemoCue WBC analyzer at the lab location. Values should compare within 15% to meet the requirements for successful calibration verification.

Quality Control:

R&D WBC Control:

- Run 3 levels (Low, Normal, High) of external controls **each day of testing.**
- 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 cloudy and reddish; 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 WBC 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 control vial. Using a transfer pipette, place a drop of control onto parafilm.
- 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 microcuvette should be filled in one continuous motion, with no air bubbles. If there are air bubbles, discard microcuvette and begin again.
- 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.
- 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 gently touch the cuvette moving arm. It will automatically slide to 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 3 minutes the result will be displayed.
- 11. Record the result on the HemoCue WBC 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 three blinking dashes with the HemoCue symbol. This indicates that the analyzer is ready for use.
3. Take the microcuvette out of the canister. Reseal the canister immediately. 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 on 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 gently touch the microcuvette moving arm. It will automatically slide into the measuring position. The filled microcuvette should be analyzed immediately and at the latest, 40 seconds after it has been filled.
8. During measurement an hourglass symbol will display. The result will display in approximately 3 minutes.
9. Record the result on the patient log sheet.
10. Remove the microcuvette from the analyzer 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 0.3-30 k/ul.
2. Values of <2.0 k/ul or > 25.0 k/ul must be repeated to verify result. Attach –pckd to the test.
3. Results that are flagged with delta check failures must be repeated. Attach –pckd to the test.
4. Results of <1.0 should be reported as preliminary results only. Send sample to Central lab for verification of low WBC. Refer to computer entry on page 6.
5. Low values will be indicated by LLL and high values as HHH. Samples exceeding the linearity must be sent to Central lab for testing.
6. Operating temperature 18-30°C
7. Operating humidity ≤ 90%
8. Mixing blood for too long a period can produce increased oxygen pressure and viscosity that may give falsely high readings.
9. 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.
10. Gloves are to be worn during the collection of the specimen and processing of the test.
11. Contents of the control vial should not be allowed to directly contact the HemoCue microcuvette due to possible back transfer of reagent.
12. For Technical Service on the instrument, call 1-800-426-7256.
13. For Technical Service on the R&D WBC Controls, call 1-800-523-3395
14. Document all trouble shooting, including trouble shooting of function checks and out of range controls on the QC logsheet.
15. Studies have shown that patient samples with < 2% nucleated red blood cells (NRBCs) may give falsely elevated white blood cell counts.

IV: MAINTENANCE

Daily: Clean the Cuvette holder

1. Turn off the analyzer.
2. Pull the microcuvette holder out to the loading position.
3. Remove the cuvette holder by lifting it straight up.

4. Clean the microcuvette holder with a cotton tipped applicator moistened with alcohol. Set it aside to dry.
5. Wait 15 minutes before replacing the cuvette holder and using the analyzer.
6. Run all three levels of controls before performing patient tests.
7. Record the cleaning on the maintenance log.

As needed: Clean the OPTICS or cover of the HemoCue analyzer

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.
2. If the following errors are indicated the optical area must be cleaned.
 - a. ERR30
 - b. ERR62
3. To clean the OPTICS
 - a. With the Microcuvette holder removed from the analyzer, insert a HemoCue cleaner into the opening of the cuvette holder. Move from side to side 5-10 times. If the cleaner is stained, repeat with a new cleaner.
 - b. Wait 15 minutes before re-inserting the cuvette holder. Make sure the cuvette arm is in its loading position before re-inserting the cuvette holder.
 - c. Run all three levels of controls before performing patient tests.

REPORTING RESULTS

Clinic Labs: see the Computer Entry section of this procedure

REFERENCES

HemoCue WBC Operating Manual.
HemoCue WBC Microcuvettes Package Insert
R&D Systems Inc. WBC Control package insert, Rev 1/10

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

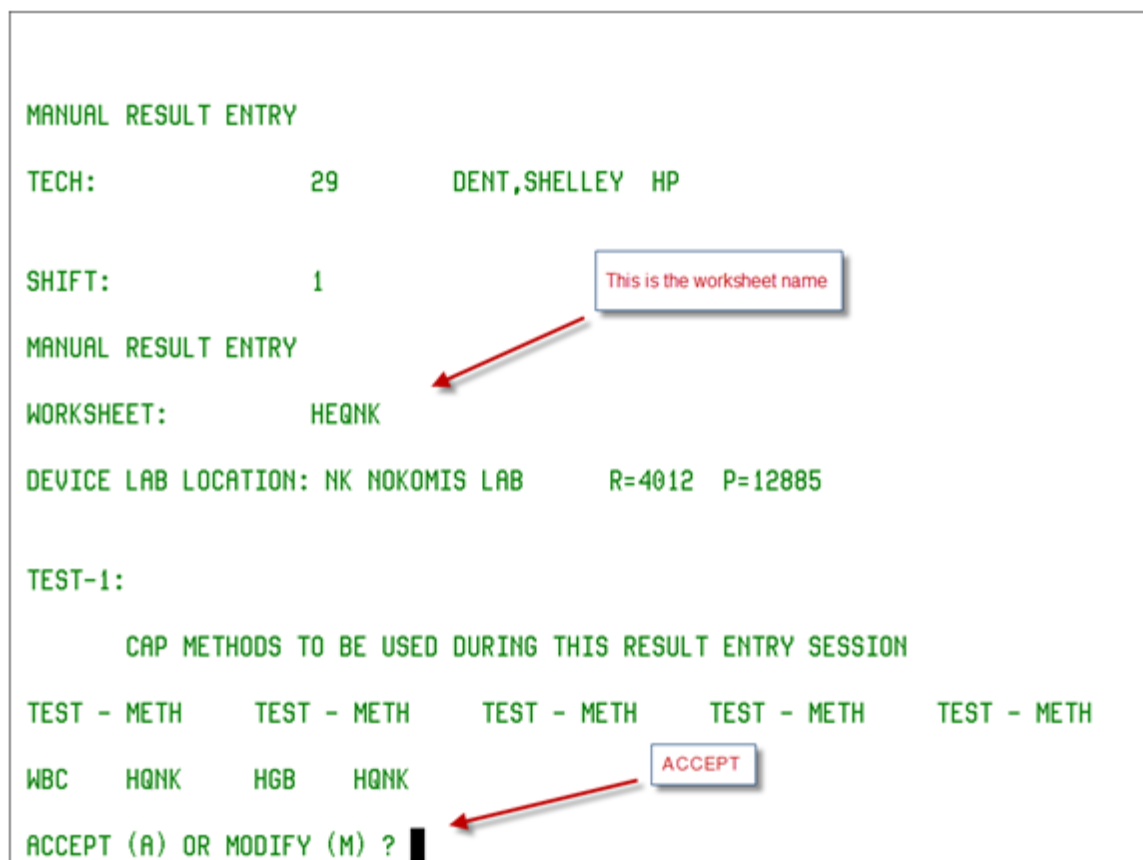
Laboratory Administration

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>
WBC	White Blood cell count	Enter the number directly to one decimal point, ie; 9.6 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 WBC result is <1.0 or exceeds the linearity limits (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 WBC 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 ;WBC <1.0 ; WBC >30.0
HCALL	Result called to	Free text who received the results. Enter first and last names, date and time. Example; WBC 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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