



MDCH/WIC Division

# Laboratory Procedure Manual

DCH-0476

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**Appendix A: Guide to Infection Prevention in Outpatient Settings:  
Minimum Expectations for Safe Care**

**Appendix B: WIC Daily Client Log: Hemocue (DCH-1489)**

**Appendix C: WIC Hemocue QC Log (DCH-1488)**

**Appendix D: Hemocue Hb 201+ Operating Manual**

## **FOREWORD**

The purpose of this manual is to provide guidance to staff in WIC programs who routinely perform blood samples as a part of WIC services. WIC acknowledges the responsibility to provide optimal care for its clients by maintaining the standards of the Michigan State Regional Laboratory System, including standards used in blood screening for iron deficiency and in maintaining a meaningful Quality Assurance Program.

This manual is based on selected information from the Quality Assurance requirements of the Michigan State Regional Laboratory System and the National Committee for Clinical Laboratory Standards.

The goal of this manual is to provide staff with direction on performing hematology screens for low serum iron. Detailed procedures are provided to outline the necessary steps in performing hemoglobin determination by HemoCue Hemoglobin Analyzer. Laboratory Training is also provided periodically by the Michigan WIC Program. Staff are referred to the local agency's policies and procedures related to Blood Borne Pathogens, OSHA and MIOSHA standards as an adjunct to the procedures stipulated here.

## **GENERAL INFORMATION FOR CAPILLARY SAMPLING**

The physical facility must provide a restroom convenient to the laboratory area. A sink with running water, preferably hot and cold, must be accessible for hand washing during blood sampling procedures. Presence of food, eating, drinking or smoking is not allowed in the lab area. Sharp items used for blood testing procedures must be discarded in a puncture-resistant container according to Universal or Standard Precautions (Appendix A: Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care).

WIC clients or their responsible parties must sign the Michigan WIC Client Agreement (DCH-0172) form that gives consent for WIC health screening including blood iron. Clients must be asked if there is a history of bleeding problems or allergy to latex prior to blood sampling. If the answer is yes, local agency procedures must be followed.

This laboratory manual does not promulgate procedures concerning what to do if a client has a reaction to blood sampling or for Universal Precautions. The WIC staff should refer to their local agency's policy and procedure for handling blood products. Refer to Appendix A: Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care for additional information.

## **I. QUALITY ASSURANCE WITH CAPILLARY SAMPLING**

Quality Assurance (QA) is a continuous process requiring monitoring and evaluation of the quality of care being provided to clients, identification of problems and delineation of appropriate actions to be taken to improve the care being given. QA includes developing and implementing procedures which assure optimal care is being provided in delivery of services based on: current standards, cost-containment, efficiency, efficacy (effectiveness in meeting goals), timeliness, accuracy, and safety.

The QA procedures which are required for WIC clinics are in accordance with the Quality Assurance standards for the HemoCue Hemoglobin Analyzer. WIC staff will comply with all Quality Assurance procedures.

In addition, all WIC agencies and clinics will follow WIC Policy 2.16 Hematological Risk Determination in regards to low serum iron risk criteria for WIC eligibility. Any referral for a low serum iron level shall be documented in the individual client record according to local agency procedure.

### **A. Quality Controls**

All local WIC clinics are required to perform the quality control procedures specified for each of the hematological tests. Quality control records must be complete, timely and accurately documented. When problems are noted while performing quality control procedures, they shall be documented in the quality control log. Documentation shall also include actions taken to correct problems.

Quality Control (QC) records will be maintained for a period of three years and 150 days.

### **B. Recording Results of Quality Control (QC) Tests**

Quality control records must include logs which document that each of the quality control procedures has been done.

At a minimum, quality control records must include:

- 1) Clinic logs which identify the client, test results and the daily self test. (See example log on Appendix B: WIC Daily Client Log: Hemocue DCH-1489).
- 2) Log of weekly testing of high and low QC material (See Appendix C: WIC Hemocue QC Log DCH- 1488).

In addition, all test results (including retests) are recorded in the individual client's record in MI-WIC.

Quality Control information for various tests must be documented in the Quality Control log each time the tests are performed. When a Quality Control test indicates a problem, the source of the problem is identified and corrective actions are documented in the Quality Control log.

Quality control logs must be reviewed on a routine basis to verify:

- quality control testing is being conducted
- documentation is complete
- actions are taken when results are outside expected ranges
- the name/initials of the persons performing the quality control testing are properly recorded.

Data must be reviewed to identify trends which may indicate faulty equipment or techniques being used in performing the tests. The individual reviewing the records must sign to verify the contents of the record are complete and that appropriate actions have been taken.

Quality Control logs will include the following information:

- a. Name of the test at the top of the sheet
- b. Date quality control testing was done
- c. Name of manufacturer, lot number, expiration date and expected result of controls which are used.
- d. Observed results
- e. Pass or fail
- f. Initials or name of the person performing the quality control test
- g. Corrective action section noting what was done when quality control tests were not within expected ranges.
- h. Date and signature of the person assigned to review the data at the bottom of the sheet, indicating the data was reviewed for accuracy, analyzed for trends and reviewed for appropriateness of actions taken in response to identified problems.
- i. The reagent assay reference document (or a copy) should be attached to the log.

Quality control records for the previous two months must be maintained at the testing site. Older records are maintained by the site supervisor in a central location for three years and 150 days.

## C. Safety

Since blood is a primary carrier for hepatitis C virus (HCV), hepatitis B virus (HBV), and human immunodeficiency virus (HIV), standard (universal) precautions are required. Use standard precautions as outlined in the local agency Bloodborne Pathogen Plan. NOTE: Standard precautions are guidelines that combine the major features of “universal precautions” and “body substance isolation” practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens.

- Place sharps container close to the collection site.
- At all times during the procedure, wear disposable gloves, lab coats, scrubs, gowns or other fluid-proof aprons and other appropriate personal protective equipment (PPE) as indicated.
- Practice hand hygiene using hand rubs or handwashing before putting on gloves and again after removing and discarding gloves.
- Change gloves for each client.
- Supplies such as cotton balls, gauze and gloves that are soaked with blood must be disposed of as biohazardous waste. If not soaked with blood, these supplies may be discarded into routine trash containers.
- It is not advisable to apply adhesive bandages over skin puncture sites on children less than two years old. Adhesive bandages can cause irritation to an infant’s skin, and an older infant might remove the bandage, put it in his/her mouth, and choke. Bandages can also be ingested by older children.
- Control solutions are blood products and require that standard precautions be utilized when handling.

## D. Specimen Collection: Blood Collection by Finger Puncture and Heel Stick

Blood should be collected from the finger of adults and children over one year old. Blood should be collected from the heel of infants less than one year old or premature infants over the age of one year who have not yet started walking.

### 1. Materials and Equipment Needed:

- Disposable latex gloves (Use non-latex, such as nitrile and/or vinyl, if the employee and/or client has a latex allergy).
- Alcohol, lint- free tissues (Kimwipes), gauze squares, or alcohol prep pads. Do not use cotton balls except to prep the puncture site.
- Blood lancets for finger puncture, capable of making a puncture to the depth of 1.5 mm
- Blood lancets designed for heel sticks on infants and premature babies, capable of making a puncture to a depth of less than 2.0 mm (e.g. BD Quikheel™ Lancet).

- Puncture resistant sharps containers
- Adhesive bandages (optional)
- Microcuvettes
- Disinfectant, such as freshly prepared 10% household bleach, for work surfaces
- Other personal protective equipment, e.g., full length lab coat or scrubs

## 2. Procedure

### a. Fingerstick:

- 1) Correctly identify and reassure the client. Explain the procedure and verify that the client does not have a bleeding disorder and is free of latex allergies (if latex products are used). Determine if the child sucks his/her fingers prior to sampling. If so, identify which fingers are sucked and avoid using those fingers for the sampling.
- 2) Position the client in a chair suitable for capillary puncture. If the client is an infant or small child, instruct the parent how best to support the child and restrain excessive movement.
- 3) Thoroughly clean your hands with hand rub or warm soapy water and apply gloves.
- 4) Obtain the sample from the third or fourth (middle or ring) finger. The WIC program, in keeping with the recommendations of the Clinical Laboratory Standards Institute (CLSI), does not recommend obtaining a specimen from the ear lobe or toe. Choose a site that is on the side of the fingertip, midway between the edge and midpoint of the fingertip. The puncture should be made perpendicular to the fingerprint ridges (shown in figure 1). Do not puncture too close to the nail bed.
- 5) Completely cleanse the chosen site with 70% isopropyl alcohol. Allow the skin to air-dry. Wet alcohol remaining on the skin will sting the client and may dilute the sample or cause rapid hemolysis (excessive breakdown of red blood cells).

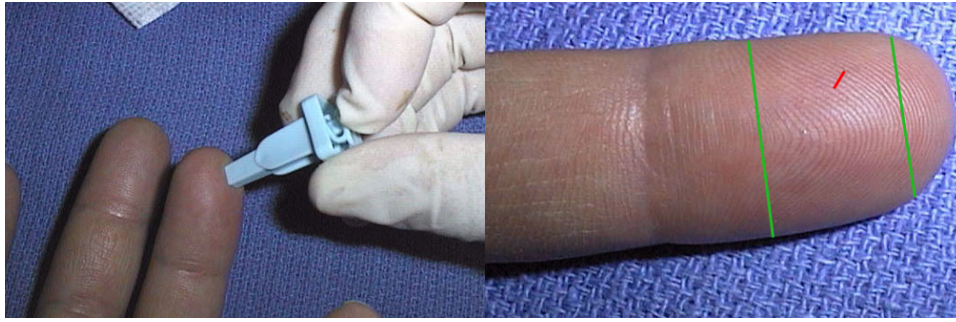


Figure 1

Figure 2

- 6) Perform finger puncture. Using a sterile, single-use retractable, disposable lancet, press firmly. Press the trigger to make a deep puncture (1.5 mm) at the chosen site (figure 2). The blood will form a bead and make collection easier. A puncture parallel to the ridges tends to make the blood run down the ridges and will hamper collection.

*NOTE: A deep puncture is no more painful than a superficial one. It gives a much better flow and makes repetition of the procedure unnecessary.*

- 7) Immediately dispose of contaminated lancet into a sharps container.
- 8) Using dry gauze, wipe away the first two drops of blood, making certain the area is completely dry. The first two drops are most likely to contain excess tissue fluid.
- 9) Wait for the formation of a large enough blood droplet to adequately fill the microcuvette; apply gentle pressure with the thumb and ease the pressure intermittently as drops of blood begin to form.

*NOTE: Do not use excessive pressure or heavy massaging because the blood may become diluted with tissue fluid or hemolysis of blood cells may occur.*

- 10) Release this pressure immediately to allow recirculation of the blood.
- 11) Collect the blood sample in the microcuvette.
- 12) Apply a piece of gauze or cotton ball to the puncture site, using slight pressure until the bleeding has stopped. For older children and adults, offer an adhesive bandage. Never place an adhesive bandage on a finger that the child routinely sucks.
- 13) Remove gloves and thoroughly clean your hands with hand rub or warm, soapy water.

b. Heelstick:

- 1) Infants (less than one year old) and premature infants over the age of 12 months who have not begun to walk are recommended to have blood collected from the heel (CLSI).
- 2) Thoroughly clean your hands with hand rub or warm soapy water and apply gloves.
- 3) Clean the infant's heel with 70% isopropyl alcohol. Allow the heel to air dry.
- 4) Using a lancet or heel incision device, perform the puncture on the plantar surface of the heel (the shaded area in figure 3). The WIC program, in keeping with the recommendations of the Clinical Laboratory Standards Institute (CLSI), does not recommend obtaining a specimen from the toe. Do not perform punctures on the posterior curvature of the heel where the calcaneus (heel bone) is close to the skin surface. The puncture should be made to a depth of less than 2.0 mm with a sterile lancet or incision device (figure 4).

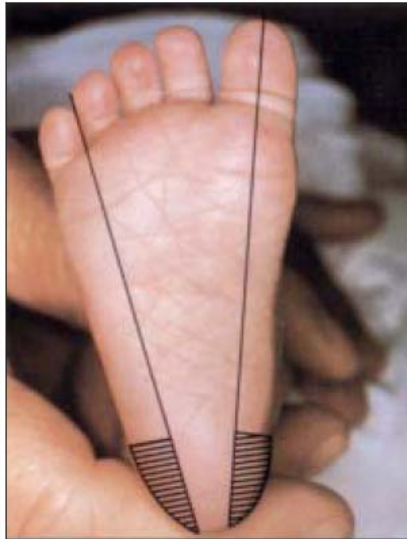


Figure 3



Figure 4

- 5) Gently wipe off the first two drops of blood with sterile lint-free gauze. The initial two drops contain tissue fluids that may dilute the sample.
- 6) Wait for the formation of a large enough blood droplet to adequately fill the microcuvette; apply gentle pressure with the thumb and ease the pressure intermittently as drops of blood begin to form.

*NOTE: Do not use excessive pressure or heavy massaging because the blood may become diluted with tissue fluid or hemolysis of blood cells may occur.*

- 7) Collect the blood sample in the microcuvette.
- 8) After blood collection is complete, elevate the infant's foot above the body and apply pressure using sterile gauze until bleeding has stopped. Do not apply adhesive bandages.
- 9) Remove gloves and thoroughly clean your hands with hand rub or warm, soapy water.

### **3. Procedural Notes**

- a. Hemolyzed specimens may cause inaccurate results. Hemolysis may occur in skin puncture blood for the following reasons:
  - 1) There is residual alcohol at the skin puncture site.
  - 2) Patients have increased red blood cell fragility and high packed cell volume (e.g., newborns and infants).
  - 3) There is milking of the puncture site.
- b. Skin puncture blood is a mixture of undetermined proportions of blood from arterioles, venules, capillaries, and interstitial and intracellular fluids. The arterial portion can be increased by warming the site prior to collection. This increases the blood flow as much as sevenfold.
- c. Do not puncture the fingers of infants less than one year old.
- d. When heelsticks are performed, take the following precautions:
  - 1) Do not puncture deeper than 2.0 mm.
  - 2) Do not puncture through previous puncture sites.

References:

- a. Specimen Collection: Blood Collection by Finger Puncture and Heel Stick, R.L.04.02, Michigan Regional Laboratory System, May, 2008
- b. *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition*. CLSI document H04-A6 [ISBN 1-56238-677-8]. Clinical Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2008.
- c. *Blood Collection on Filter Paper for Newborn Screening Programs*. National Committee for Clinical Laboratory Standards, Vol. 23. No. 21 Approved standard – Fifth Editions, CLSI Document LA4-A5 (ISBN 1-56238-644-1). Clinical Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007.

## II. HEMOGLOBIN DETERMINATION

"Anemia is said to exist when the level of circulating hemoglobin in the patient is lower than that of healthy persons of the same age group and sex in the same environment"(WHO). The most common type of anemia is iron deficiency, which may be caused by inadequate iron intake, insufficient assimilation of iron from the diet, the increased utilization of iron during periods of rapid growth or pregnancy, or blood loss. Anemia can impair energy metabolism, temperature regulation, immune function and work performance. Anemia during pregnancy may increase the risk of prematurity, poor maternal weight gain, low birth weight and infant mortality. In infants and children, the greatest risk from iron deficiency anemia is a delay in mental and motor development. Measurement of hemoglobin concentration is used to detect the presence of anemia or presumed iron deficiency among participants in the WIC Program.

### A. Invasive Technique Using HemoCue Hb 201+

#### 1. Materials

##### a. Instruments

- HemoCue Hb 201+ Analyzer
- HemoCue AC Adapter or 4 AA alkaline batteries
- HemoCue Hb 201+ manual

##### b. Supplies

- HemoCue Hb-201+ Microcuvettes (50/vial and/or 200/box) (cat. # 111710)
- HemoCue Hb-201+ Individually Packaged Microcuvettes (100/box) (cat. # 111715)
- Gloves (disposable latex, nitrile and/or vinyl gloves)
- Alcohol, lint-free tissues (Kimwipes), gauze squares, or alcohol prep pads. Do not use cotton balls to prep puncture site.
- Blood lancets for finger puncture, capable of making a puncture to the depth of 1.5 mm
- Blood lancet designed for heel sticks on infants and premature babies, capable of making a puncture to a depth of less than 2.0 mm (e.g. BD Quikheel™ Lancet).
- Puncture resistant sharps containers
- Disinfectant
- Liquid controls for HemoCue instruments that measure hemoglobin: HemoCue has determined that the following controls are compatible with their instrumentation. Each agency must choose which of these control materials to order and use at their

clinic(s).

- BioRad Meter Trax™ hemoglobin controls
- R&D Glu/Hgb Controls: R&D Systems, Inc., Minneapolis MN
- HEMA-Trol™ Whole Blood Hgb Controls: Nerl Diagnostics, East Providence, RI
- HemoTrol: Eurotrol® hemoglobin controls, (available for purchase through HemocCue).

c. Supply Storage and Stability

- 1) Controls - Refer to the manufacturer package insert for specific storage criteria.

*NOTE: If controls are stored in the refrigerator, they must be returned promptly to the refrigerator after testing. If controls are stored at room temperature, they must be kept in a closed container (e.g., zip-lock bag) since they are a blood product.*

- a) Unopened controls are stable until the expiration date specified by the manufacturer when stored in the refrigerator (2-8°C or 35-46°F).
- b) Once opened, control vials may be stored in either the refrigerator or at room temperature, provided they are handled properly.
- c) When opened, write both the date opened and the open vial expiration date on the vial.
- d) The length of time a control is stable after opening (the open vial expiration date) is specified by the manufacturer. Read the package insert and strictly adhere to the manufacturer's guidelines. For example:
  - BioRad Meter Trax Controls are stable for 31 days after opening when stored in the refrigerator or at room temperature.
  - R&D Glu/Hgb are stable for 30 days after opening when stored in either the refrigerator or at room temperature.
  - HEMA-Trol Controls are stable for 60 days after opening if stored in the refrigerator or for 30 days if stored at room temperature.
  - HemoTrol (Eurotrol) controls are stable for 30 days after opening when stored at room temperature.

*NOTE: This material has an 18 month shelf life after manufacture when stored at refrigerator temperature. In a letter dated March 2008, the company announced the extension of the refrigerated shelf life of unopened HemoTrol control by 6 months, from 12 months to 18 months.*

- 2) Microcuvettes - Store the microcuvettes at room temperature (15-30 °C or 59-86 °F) in a dry location.
  - a) The individually wrapped microcuvettes have an expiration date specified by the manufacturer and printed on the outside of each individual packet.
  - b) The bulk microcuvettes have an expiration date specified by the manufacturer and printed on the outside of the vial. Once opened, the microcuvettes are stable for three (3) months. Tightly reseal container immediately after use. Write both the date opened and the open vial expiry date on the container.
- 3) HemoCue Hemoglobin Analyzer - Remove the batteries from the analyzer if it will be stored for more than a week.

## 2. Quality Control (QC)

### a. Machine Quality Assurance

- 1) The HemoCue 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.

*NOTE: The SELFTEST does not eliminate the need for Liquid Control testing.*

### b. Liquid Controls

Both a high and a low liquid control must be run each week (Monday-Friday/Saturday) of testing before any client samples are analyzed. This ensures the proper functioning of the instrument, the integrity of the microcuvettes, and that the analyst is performing the test accurately.

- 1) Frequency:
  - a) A high and a low liquid control must be run once a week on each HemoCue analyzer in the laboratory prior to client testing.
  - b) A high and low liquid control must be run to check each new lot number of microcuvettes before they are used for client testing.
- 2) Ideally, responsibility for running weekly controls should be distributed among all staff so that each analyst will be performing QC on a regular basis. The use of a “designated QC analyst” who performs all QC activities at a clinic is discouraged.

3) Procedure for liquid control use:

Carefully mix the liquid control reagents while bringing them to room temperature by rolling them between the palms of the hands and inverting gently several times. The blood cells should not cling to the bottom of the vial when they have been properly mixed. NEVER SHAKE vials. To obtain a good sample, place one drop of control solution on a non-permeable (non-penetrating) material such as tape, alcohol prep pad wrapper, or plastic and then insert the tip of the microcuvette into the drop.

4) Expected values:

- a) The maximum acceptable range for each liquid control will be listed on a specification sheet included with each set of vials. The analyst must ensure that both the daily self test and weekly liquid controls are within the expected range before client testing is performed.
- b) Retain a copy of the manufacturer's package insert for each lot number of liquid control solutions. It should be possible to verify that the expected range of the control matches the lot number and expected ranges entered on the laboratory QC sheet. This copy should be retained with the corresponding QC sheets for 3 years and 150 days.

5) Corrective action:

- a) The self-test and liquid controls must be repeated if the self-test is unsuccessful or the observed results of the controls fall outside acceptable limits.
- b) If the self-test consistently fails to read according to specifications, clean the interior chamber of the instrument. If the failure continues, notify your supervisor and call HemoCue technical service for further instructions. DO NOT test any client samples if the optic check fails.
- c) Contact information
  - HemoCue Tech Support: 800-426-7256 6:00am -5:00pm PST
  - Ryan Diagnostics Tech Support: 800-352-3252 9:00am - 5:00pm EST
- d) If the low and high liquid controls fail to read within expected range, they should be repeated. A second failure suggests that

either the cuvettes are damaged or that the liquid controls have been damaged. A troubleshooting outline may be found in Appendix D Hemocue Hb 201+ Operating Manual.

- e) If the Quality Control checks fail, it is important to document on the QC log sheet that corrective action was taken.

c. Maintenance Schedule

- 1) Clean the exterior of the instrument on a daily basis with a clean cloth which has been slightly dampened with alcohol or a mild disinfectant soap solution. Allow the disinfectant 1-2 minutes contact time. Wipe off remaining disinfectant with a damp cloth. Do not use abrasives at any time.
- 2) Clean the interior of the analyzer and lens assembly daily (or each day that the instrument is in operation).
  - a) Turn the Analyzer off.
  - b) Wet the ends of 3 cotton swabs with **water** and squeeze out excess water until the tips are only moist.
  - c) Note: Alcohol is not to be used in cleaning the interior of the analyzer and lens assembly.
  - d) Remove the cuvette holder, pulling it straight out.
  - e) Using a moist swab, insert the swab approximately 4-6 cm. into the center of the analyzer's cuvette opening and clean both the upper and lower surfaces. Pay particular attention to the lens assembly which is located on the top surface; it is about 1 cm. wide and 4.5 cm. into the chamber (figure 5).

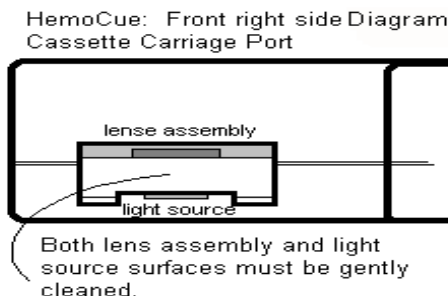


Figure 5

- f) Repeat the procedure with the next several swabs until no more blood or dust can be removed.

- g) Dry the interior with a clean dry swab.
- 3) The microcuvette holder should be cleaned daily with alcohol or a mild soap solution and allowed to air dry before reinserting. The microcuvette holder should be cleaned at the end of each day that testing is performed so that it will be ready for use the next morning.
- 4) For more thorough cleaning instructions, refer to Appendix D.

### 3. Method:

- a. Self-test HemoCue 201+ - performed automatically each time the analyzer is turned on.
  - 1) Attach the AC-adaptor to the analyzer power inlet.
  - 2) Plug the AC-adaptor into the wall outlet.
  - 3) Turn the HemoCue Hb 201+ power switch to the ON position, located on the back of machine.
  - 4) Pull the cuvette holder out to the loading position.
  - 5) Press and hold the left button until the display is activated (all symbols appear in the display). The display will show an hourglass and “Hb”. The SELFTEST will start automatically.
  - 6) 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. Upon passing the SELFTEST, the display will show the HemoCue symbol and three flashing dashes, indicating that the analyzer is ready to perform a measurement. An error code will be displayed if the SELFTEST fails.
  - 7) Record results (pass/fail) of the SELFTEST on the daily Quality Control log sheet and then perform weekly QC, if necessary.
- b. Weekly QC with Liquid Controls

*NOTE: Liquid controls are blood products requiring that standard (universal) precautions, including the use of gloves, be observed when handling.*

  - 1) Warm both liquid control vials (low and high) to room temperature for 15-30 minutes before mixing.

- 2) Hold vial upright and roll the vial slowly between palms several times.
- 3) Gently invert the vial 8-10 times immediately before sampling.
- 4) Inspect vial contents to ensure that cells have been uniformly distributed.

*NOTE: If the control is not uniformly distributed, the dilution of the vials may be altered, affecting the accuracy of the test result.*

- 5) Repeat steps 2-4 if uniform distribution is not observed.
- 6) Remove cap from vial. Dispense one drop of the control onto a non-permeable (non-penetrating) material such as tape, alcohol prep pad wrapper or plastic. Insert the tip of the microcuvette into the drop.
- 7) Hold the microcuvette at the “wing” end and touch the tip into the middle of the drop of control material. Fill in one continuous process. Do not refill a partially filled microcuvette.
- 8) Wipe any residual control material from the sides of the microcuvette with a piece of gauze, as if wiping excess butter from a knife. Do not touch the opened end with the gauze since this will draw blood out.
- 9) Visually inspect for air bubbles in the center of the cuvette eye. If bubbles are present in the eye, discard the microcuvette and obtain another specimen.
- 10) Place the filled microcuvette into the holder and gently slide the holder into the measuring position in the instrument. Filled microcuvettes are to be kept in the horizontal position.

*NOTE: The liquid control solutions are different from human blood. Therefore after loading the microcuvette and placing the microcuvette into the holder, it is essential to wait 1-2 minutes before pushing the sample into the instrument and taking a reading.*

- 11) The hemoglobin value will be displayed in grams/dL after approximately 30-50 seconds.
- 12) Document the result on the QC sheet.
- 13) Remove the microcuvette from the instrument and discard into a biohazard sharps container.
- 14) Verify that all controls (daily self test and weekly low and high external liquid controls) are within acceptable limits before client testing is performed.

c. Procedure for Client Testing

- 1) Seat the client comfortably.
- 2) Clean your hands with hand rub or soap and water and put on gloves.
- 3) Ask the client or responsible adult if they have a bleeding disorder or other medical condition that would contraindicate testing.
- 4) Ask the client or responsible adult if there is a known allergy to latex. If allergy exists, non-latex gloves must be worn for the procedure.
- 5) Select an appropriate puncture site. For best results, use the middle finger or the ring finger for sampling. Avoid fingers with rings for sampling.
- 6) If client's fingers are cold, have client rinse with warm water. The client's fingers should be straight but not tense.
- 7) Remove a microcuvette from the vial and recap the vial immediately.
- 8) Clean site for blood collection with alcohol-soaked gauze or a newly-opened alcohol prep pad.
- 9) Using your thumb, lightly press the finger from the distal knuckle (phalanx) to the tip to stimulate flow of blood to the sampling point. For the best blood flow and the least pain, sample midway between the edge and midpoint of the fingertip.
- 10) The puncture should be made perpendicular to the fingerprint ridges.
- 11) Press the lancet firmly off-center on the fingertip prior to activating the lancet to aid in obtaining a good sample.

***NOTE:** If a heel stick is to be performed to collect blood from a newborn infant, refer to page 10.*
- 12) Activate the lancet to puncture the fingertip. Discard the lancet in an approved sharps container.
- 13) Wipe away the first two large drops of blood. This stimulates the blood flow and lessens the likelihood of a dilutional effect by interstitial fluid. If necessary, apply light pressure again, until another drop of blood appears. Avoid "milking of the finger".
- 14) Make sure the third drop of blood is big enough to fill the microcuvette completely. Hold the microcuvette at the "wing" end and touch the tip into the middle of the drop of blood from above the finger. Avoid touching the microcuvette to the skin. Keep the

microcuvette in contact with the blood and fill in one continuous process. Do not refill a partially filled microcuvette.

- 15) Wipe any residual material from the sides of the microcuvette with a piece of gauze, as if wiping excess butter from a knife. Do not touch the opened end of the microcuvette with the gauze since this will draw blood out of the microcuvette.
- 16) Visually inspect for air bubbles in the center of the microcuvette eye. If bubbles are present in the microcuvette eye, discard the microcuvette and obtain another specimen.
- 17) The microcuvette should be analyzed within 10 minutes after being filled. Filled microcuvettes are to be kept in the horizontal position. Place the filled microcuvette into the cuvette holder and gently slide the holder into the measuring position.
- 18) During the measurement, the hourglass symbol and three fixed dashes will be shown on the display.
- 19) The Hgb value will be displayed in grams/dL within 30 to 50 seconds.
- 20) Record result before removing the microcuvette from the instrument.
- 21) Pull the microcuvette holder out to the loading position. Remove the microcuvette and discard it into the biohazardous waste container.
- 22) When the display shows three flashing dashes and the HemoCue symbol, the analyzer is ready for the next measurement.
- 23) If an "ERROR" code is displayed, refer to Appendix D.
- 24) Apply a piece of gauze (or cotton ball) to the puncture site, using slight pressure until the bleeding stops. For older children and adults, offer an adhesive bandage. Never place an adhesive bandage on a finger that the child routinely sucks. To assure child safety, remind the caretaker to watch the child closely to be sure the bandaged finger is not put into the child's mouth. Suggest that the adhesive bandage be removed before leaving the clinic.
- 25) Remove gloves and clean hands with hand rub or soap and water.

*NOTE: A sink with running water must be accessible for immediate handwashing during blood sampling procedures.*

d. Criteria for Client Testing

- 1) MI-WIC Policy 2.16 (effective date 1/19/10) provides guidance for

testing of women and children.

- 2) MI-WIC Policy 2.13A (effective date 9/24/10) lists the cutoff levels for low hemoglobin values for women and children (See section 8. Results, B and C of this manual).
- 3) Client Retesting:
  - a. Each agency must have a written policy that establishes a re-testing procedure from the following options:
    - Testing levels that are outside the cutoff values specified in Policy 2.13A Nutrition Risk Criteria.
    - A critical hemoglobin result (<8 or >17 g/dL)
    - Testing levels that have been specified as a critical value established by local agency policy
  - b. Retesting must be done immediately.
    - Repuncture at a new site.
    - Document both results and comments into client's MI-WIC record.
  - c. A third retest is not recommended.

#### **4. Recordkeeping**

##### a. Clinic Logs:

- 1) Sufficient information must be recorded to ensure that the client is identified and that one can trace the result from the clinic log to the client record. Complete the WIC Daily Client Log: HemoCue (See Appendix B).
- 2) The lot number and expiration date of the HemoCue Hb analyzer microcuvettes must appear at the top of the log. In the case of a reagent recall, it should be possible to identify which clients were tested with a specific lot number of microcuvettes.
- 3) Record all client results on the Daily Client Log.
- 4) The daily self test must be documented each day of testing.

##### b. Quality Control (QC) Logs:

- 1) Complete top section of HemoCue QC log. Record the expiration dates and lot numbers of the microcuvettes, low controls, and high controls on the QC log sheet (See Appendix C).
- 2) Enter the expected ranges for the low and high controls on the QC log sheet.

- 3) Record the results of the Self Test as either Pass or Fail on a daily basis on the WIC Daily Client Log.
  - 4) Document the results (Pass or Fail) of the daily self test and weekly high/low controls.
  - 5) The site supervisor will review and sign the QC log at the end of the month.
- c. Daily Client and QC logs for the previous two months must be maintained at the testing site. Older records are maintained by the site supervisor in a central location for three years and 150 days.
  - d. Retain a copy of the manufacturer's package insert for each lot number of liquid control solutions with the corresponding QC logs. It should be possible to verify that the expected range of the control matches the lot number and expected ranges entered on the laboratory QC sheet.
  - e. In the case of a reagent recall, it should be possible to identify which clients were tested with a specific lot number(s) of microcuvettes or controls.

## **5. Limitations of Method**

- a. The quality of the sample has a considerable effect upon the accuracy and precision of this test. Examine the sample drawn into the microcuvette. Bubbles of any size in the circular optical eye are unacceptable. If bubbles are present, discard the microcuvette and obtain another sample.
- b. Exposure to moisture in room air will inactivate the reagents in the microcuvette. Take only one or two microcuvettes out of the canister (what you will use within 5 to 10 minutes). Do not return any microcuvettes to the storage canister and keep the canister lid tightly closed at all times.

## **6. Procedural Notes**

- a. The HemoCue 201+ Hemoglobin 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, only controls that are assayed for the HemoCue Hemoglobin systems are recommended.
- b. Results above 25.6 gm/dL will be displayed as ERROR 999 or ERROR HHH. Refer to the Trouble Shooting Guide in Appendix D for interpretations of other error codes.

**7. Sources of Error and Recommended Actions**

- a. Bubbles in the sample: The quality of the sample has a considerable effect upon the accuracy and precision of this test. Examine the sample drawn into the microcuvette. Bubbles of any size in the circular optical eye are unacceptable. If bubbles are present, discard the microcuvette and obtain another sample.
- b. Microcuvettes exposed to moisture: Exposure to moisture in room air will inactivate the reagents in the microcuvette. Take only one or two microcuvettes out of the canister (what you will use within 5 to 10 minutes). Do not return any microcuvettes to the storage canister and keep the canister lid tightly closed at all times.
- c. Microcuvettes exposed to excessive temperatures: Store microcuvettes in their canister at room temperature. Monitor the temperature of the room in order to detect fluctuations of temperature which may have a detrimental impact on the integrity of the microcuvettes.
- d. Microcuvettes expiration: The microcuvettes are stable for 90 days after opening a new canister. Write both the date opened and the open vial expiry date on the container. Discard unused microcuvettes after 90 days. Individually wrapped microcuvettes available for the HemocCue 201+ analyzer have a longer shelf life.
- e. Error Codes: If the analyzer shows “ERROR” and a digit code, turn off the analyzer and switch it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, check the Troubleshooting Guide. (See Appendix D).

**8. Results**

- a. Normal Values:

Population	Hemoglobin
Infants (full term)	10.5 – 19.5 g/dL
Children (1-9 years)	11.0 – 14.0 g/dL
Children (10-12 years)	11.5 – 15.0 g/dL
Men (Adults)	13.0 – 18.0 g/dL
Women (Adults)	12.0 – 16.0 g/dL
Pregnant Women	11.0 – 14.0 g/dL

- b. WIC Criteria for Risk Criteria 201– Women: Any value below the cutoff values at the time the specimen was taken (MI-WIC Policy 2.13A, effective 9/24/10)

<b>Status</b>	<b>Non-smoking</b>	<b>Smoking up to 19 cigarette/day</b>	<b>Smoking 20-39 cigarette/day</b>	<b>Smoking 40 or more cigarette/day</b>
Post-partum - at/over age 15	<12.0	<12.3	<12.5	<12.7
Post-partum – under age 15	<11.8	<12.1	<12.3	<12.5
1 <sup>st</sup> Trimester (0-13 weeks)	<11.0	<11.3	<11.5	<11.7
2 <sup>nd</sup> Trimester (14-26 weeks)	<10.5	<10.8	<11.0	<11.2
3 <sup>rd</sup> Trimester (27 wks or more)	<11.0	<11.3	<11.5	<11.7

- c. WIC Criteria for Risk Criteria 201– Infants and Children: Any value below the cutoff values at the time the specimen was taken ((MI-WIC Policy 2.13A, effective 9/24/10)

<b>Status</b>	<b>Value</b>
Infant: 6 – 11 months	<11.0
Child: 12 – 23 months	<11.0
Child: 24 – 59 months	<11.1

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