Michigan Department of Health and Human Services (MDHHS) Women, Infants, and Children (WIC) Division

Laboratory Manual

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Appendices

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

Appendix B: WIC Client Log: HemoCue (MDHHS-5782)

Appendix C: WIC HemoCue Quality Control (QC) Log (MDHHS-5781)

Appendix D: HemoCue Hb 301 Operating Manual

Acronyms

CLIA - Clinical Laboratory Improvement Amendments
CLSI - Clinical and Laboratory Standards Institute
CMS - Centers for Medicare and Medicaid Services
HBV - Hepatitis B Virus
HCV - Hepatitis C Virus
HIV - Human Immunodeficiency Virus
LA - Local Agency
LARA - Department of Licensing and Regulatory Affairs
MIOSHA - Michigan Occupational Safety & Health Administration
MWRA - Medical Waste Regulatory Act
PPE – Personal Protective Equipment
QA - Quality Assurance
QC - Quality Control
WHO – World Health Organization
WIC – Women, Infants, and Children

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Introduction

The purpose of this manual is to provide information to staff who routinely perform hemoglobin capillary blood testing as a part of WIC services. This manual is based on the requirements of the Clinical Laboratory Improvement Amendment of 1988 (CLIA), selected information from the State of Michigan Bureau of Laboratories Quality Assurance Section, the Clinical and Laboratory Standards Institute (CLSI) and HemoCue America. Detailed procedures are provided to outline the necessary steps in performing hemoglobin determination by a hemoglobin analyzer. Laboratory trainings are provided throughout the year by the State of Michigan WIC Division staff. Specific training dates may be found here: https://events.mphi.org/calendar.

CLIA requires that the local agency (LA) laboratory director review and approve this procedure on a yearly schedule. The LA laboratory director (or in the absence of one, WIC Coordinator) must approve all forms and logs that are used for patient testing. WIC strongly encourages the use of the forms attached to this procedure, however, if the LA laboratory director would like to revise the form(s), it must contain all the information in the forms provided.

Why screen hemoglobin levels in the WIC population?

"Anemia is said to exist when the level of circulating hemoglobin in an individual 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, 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.

Quality Assurance Overview

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 as necessary. QA includes developing and implementing procedures based on current standards, cost-containment, efficiency, efficacy (effectiveness in meeting goals), that will yield accurate, reliable and timely results.

The objectives of the QA procedures are:

- To assure that patient test results are accurate and complete.
- To encourage uniformity in testing procedures and quality assurance practices performed in all participating public health testing sites.
- To rapidly identify and correct problems encountered while following written procedures.
- To ensure that records are maintained that permit the evaluation of the quality and reliability of the data produced.
- To provide both the professional and non-professional staff with the cost-efficient procedures, reagents and equipment needed to confidently perform testing and implement this quality assurance program.
- To assure sample integrity.
- To identify needs and provide training and other resources required to maintain and improve the skills of the staff.

The QA procedures required for WIC clinics are in accordance with CLIA quality assurance requirements and follow MDHHS Bureau of Laboratories QA Section and the Department of Licensing and Regulatory Affairs (LARA) for the hemoglobin analyzer. WIC staff must comply with all QA procedures.

Clinical Laboratory Improvement Amendments

CLIA are federal regulatory quality standards for laboratory testing performed on specimens from humans, such as blood, for the purpose of diagnosis, prevention or treatment of disease and assessment of health.

A CLIA Certificate of Waiver is required for each WIC clinic location that performs hemoglobin testing. Local agencies are responsible for verifying each applicable clinic has a CLIA Certificate or Certificate of Waiver. If a WIC clinic is not included in the health department/local agency's CLIA Certificate, contact the laboratory director or designee.

The CLIA application form CMS-116 (Centers for Medicare & Medicaid Services) is required to be completed for a "**CLIA Certificate of Waiver**." Certificates are issued by the Centers for Medicare and Medicaid Services (CMS). The Michigan Department of Licensing and Regulatory Affairs (LARA), Laboratory Improvement Section reviews the applications and issues the certificate. WIC funds can be used to pay for the application fee. If the agency has a certificate of complexity (either a moderate or high complexity), please follow the CLIA requirements for that level of certificate. All four levels of certificates require the laboratory director to approve all testing, forms and QA. Refer to Federal Regulations, PART 493—LABORATORY REQUIREMENTS.

Email or fax application to:
Department of Licensing and Regulatory Affairs
Bureau of Community and Health Systems - CLIA
PO Box 30664
Lansing, MI 48909

Phone: 517-241-2648
Fax: 517-241-3354
E-Mail: BCHS-CLIA@michigan.gov

I. Standard Precautions and Safety

Since blood can be a primary carrier for infectious diseases, such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), Standard (Universal) Precautions are required. Standard Precautions shall be observed to prevent contact with blood.

The Michigan Occupational Safety & Health Administration (MIOSHA) requires WIC local agency staff to participate in a bloodborne infectious diseases training prior to doing capillary blood sampling and annually thereafter. Options to meet the bloodborne infectious diseases training requirement include completion of:

1) an online MIOSHA training, or 2) WIC Laboratory training, or 3) local agency training program, if offered, staff should refer to their local agency exposure control plan for specifics on reducing bloodborne infectious disease exposure and guidance on what to do if exposed to blood at work.

To be in accordance with Section 13827(3)(b) of the Medical Waste Regulatory Act (MWRA), part 138 of the Public Health Code, 1978 PA 368, as amended, the agency must register with the Michigan Department of Environment, Great Lakes, and Energy (EGLE) for a certificate as a producing facility of medical waste. The registration will be for the entire agency, therefore, if there is an immunization division, and a laboratory, they will both be included on the registration.

A. Hand Hygiene

1. Hand sanitizer/rub is acceptable for routine use:
    a. Before and after gloving.
    b. When hands are not visibly soiled.
2. Hands should be washed with soap (plain or anti-microbial) when:
    a. Hands are visibly dirty or soiled with blood.
    b. Before eating.
    c. after using the restroom.
3. A sink with running water must be accessible for hand washing.

B. Precautionary Steps

1. Wash hands or use hand sanitizer/rubs before putting on gloves and again after removing and discarding gloves.
2. Use personal protective equipment (PPE)
    a. Disposable gloves must be worn at all times during the procedure.
    b. Gloves must be changed after each client's test, even if the clients are members of the same family.

c. Lab coats, scrubs, gowns, eye protection or other fluid-proof aprons are *optional*.

3. Place sharps container close to the collection site. Sharp items (lancets) used for blood testing procedures must be discarded in a puncture-resistant container according to Standard Precautions.
4. Gauze wipes and gloves may be discarded into routine lined trash containers. If they are soaked or saturated with blood (capable of releasing blood if gently squeezed) they must be disposed of as bio-hazardous waste.
5. Control solutions are blood products and require that Standard Precautions be utilized when handling.
6. Presence of food, eating, or drinking is not allowed in the lab area.
7. Microcuvettes should be disposed of as bio-hazardous waste, either in a bio-hazard waste bag or in a sharps container.

C. Guide to Safety

1. This laboratory manual does not provide staff guidelines for handling client's adverse physical reactions to blood sampling, such as fainting, allergic reactions or excessive bleeding. The WIC staff should refer to their local agency's policy and procedure for handling these events.
2. For infants and children less than three years old, it is not advisable to apply adhesive bandages over skin punctures. An older infant or child can remove the bandage and it can pose a choking hazard.

II. Materials

The following items are needed to conduct hemoglobin testing, including running liquid controls.

A. Equipment and Supplies

1. HemoCue Hb 301 Analyzer
2. HemoCue AC Adapter *or* 4 AA alkaline batteries
   - Do Not keep batteries in compartment when using AC Adapter
3. HemoCue Hb 301 Operating Manual
4. HemoCue Hb 301 Microcuvettes (75/vial and/or 300/box)
5. Gloves (disposable vinyl, nitrile and/or latex gloves)
6. Alcohol or alcohol prep pads (do not use cotton balls)
7. Gauze squares or lint-free tissues (Kimwipes)
8. Safe lancets for finger puncture, capable of making a puncture at least a depth of 1.5 mm
9. 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)
10. Puncture resistant sharps containers
11. Disinfectant, such as freshly prepared 10% household bleach, for work surfaces. Note: Ensure the active ingredient in the bleach is a minimum of 5.25% Sodium Hypochlorite, as anything less will not act as a disinfectant. This solution should be prepared fresh each day of use
12. Drape/paper tissue, on which to set testing supplies
13. Liquid Controls (low & high - see below)

B. Storage

1. Liquid Controls - Refer to the manufacturer package insert for specific storage criteria.
    a. 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.
    b. 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 at room temperature in a closed container (e.g., zip-lock bag) since they are a blood product.
2. Microcuvettes - Store the microcuvettes at room temperature (50-104ºF or 10-40ºC) in a dry location.
    a. The microcuvettes have an expiration date specified by the manufacturer and printed on the outside of the vial. This is usually two years after date of manufacture. Write the date opened on the container. Do not use after expiration date.
    b. Vial must be tightly closed immediately after removing microcuvette.
3. HemoCue Hb 301 Analyzer
    a. Remove the batteries from the analyzer if it will be stored for more than a week.
    b. Acceptable operating temperature range 50-104ºF (10-40ºC)
    c. Storage and transport temperature range 32-122º F (0-50ºC)

III. Quality Control (QC)

A. HemoCue Hb 301 Self-test Procedure

1. Attach the AC-adaptor to the analyzer power inlet and plug the AC-adaptor into the wall outlet **or** insert four (4) AA Batteries.
2. Turn the HemoCue Hb 301 power switch to the ON position.
3. Pull the cuvette holder out to the loading position.
4. Press and hold the button until the display is activated (all symbols appear in the display). The SELFTEST will start automatically. After 10 seconds the display will show three flashing dashes and the HemoCue symbol. This indicates the analyzer is ready for use. If an error code displays, refer to the HemoCue Hb 301 Operating Manual for instructions.

    ***NOTE**: The HemoCue Hb 301 analyzer has an internal electronic "SELFTEST." Each time the analyzer is turned on, it automatically verifies the performance of the optronic unit of the analyzer. The self-test is performed every second hour of the day if the analyzer remains on.*
5. Record results (pass/fail) of the Self-Test on the WIC Client Log: HemoCue (MDHHS-5782), as indicated in the "Documentation and Record Retention" section of this manual. (Customization of the WIC Client Log is allowed, provided all required fields are captured and revisions are approved by the laboratory director).

B. Running Liquid Controls – Frequency

1. Both a low (level 1) and a high (level 3) liquid control must be run each week of testing before any client samples are analyzed. This ensures the proper functioning of the analyzer, the integrity of the microcuvettes and the technique of the staff performing the test.

2. Liquid controls must be run for:
    a. New HemoCue analyzer kits before they are placed in service.
    b. All new shipments of controls.
    c. New lot numbers of microcuvettes when opened.
    d. Analyzers or microcuvettes moved to offsite testing (i.e., satellite clinic, hospital).
    e. Analyzers that were *stored* outside of the required temperature range (32-122ºF).
    f. Analyzers *operating* outside of the required temperature range (50-104ºF).
3. All staff who perform Hb testing shall rotate, so that all staff shall perform QC on a regular basis. The use of one staff person performing all QC activities at a clinic is against CLIA regulations.

C. Running Liquid Controls – Procedure

1. If liquid controls are refrigerated, bring liquid controls to room temperature by removing controls from the refrigerator 15 minutes prior to testing.
2. Hold vial upright and roll the vial slowly between palms several times.
3. Gently invert the vial 8-10 times immediately before sampling. Do not shake vial; this can cause hemolysis of red blood cells.
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, indicated by observing a “button” (dark spot) on the bottom of the vial.
6. Remove cap from vial. Dispense one drop of the control onto a non-permeable (non-penetrating) bacteria-free material such as the inside of a band-aid wrapper, or a piece of plastic wrap.
7. Introduce the cuvette tip into the middle of the drop. 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 tap to close the HemoCue door for analysis.
11. The hemoglobin value will be displayed in grams/dL in approximately **3 seconds.**
12. Record the result on the WIC HemoCue Quality Control (QC) Log (MDHHS-5781).
13. Remove the microcuvette from the analyzer and discard it.
14. Verify that all controls (daily self-test and weekly low and high liquid controls) are within acceptable values before client testing is performed. The acceptable ranges for the liquid controls will be listed on the manufacturer insert included with each set of vials.

D. QC Corrective Action

1. QC Test Failure: When a QC test fails, the source of the problem should be identified, and corrective action should be taken. Document on QC log all corrective action taken to resolve the problem.
    a. If the self-test fails, refer to the HemoCue Hb 301 Operating Manual.
    b. If the low and high liquid controls fail to read within expected ranges, they should be repeated. A second failure suggests that either the cuvettes and/or the liquid controls are damaged or the optronic unit is dirty. A troubleshooting guide can be found in Appendix D: HemoCue Hb 301 Operating Manual.
    c. Contact Information - HemoCue Tech Support:
    Phone: 800-881-1611, option 2, 6:00 am - 8:00 pm EST
    Email: technicalsupport@hemocue.com

IV. Documentation and Record Retention

A. WIC Client Log: HemoCue (MDHHS-5782) must include:

1. The microcuvette lot number, date opened, and manufacturer's expiration date used for the clients recorded below. If a 2nd bottle/vial is opened, record the required information next to Cuvette #2 and mark "2" in the Notes column next to the first applicable client. (In case of a recall, it is necessary to identify which clients were tested with a specific lot number of microcuvettes.)
2. Date and results of self-test (pass/fail) for each day. (One client log may be used for multiple days.)
3. Identifiable client information (client full name or WIC client ID number). This information ensures the client is identified and can be traced from the client log to the client record**.** All client information must be stored in a confidential manner (see MI-WIC Policy 1.03, Confidentiality).
4. Client hemoglobin results (and re-tests if necessary). If an error code appears, it might be sample related and not machine related. Record the error code result in the client results and re-run the test. Also record the test result in the QC log so that trends for possible machine errors can be recorded and identified for corrective action.
5. Staff initials and printed name at bottom of the log.
    NOTE: *Staff may use the Notes column for recording Cuvette bottle number or lead test results.*

B. WIC HemoCue Quality Control (QC) Log (MDHHS-5781) must include**:**

1. Site, analyzer type, month and control manufacturer of liquid controls.
2. Liquid controls lot numbers (both low and high).
3. Date liquid controls are opened.
4. Closed and opened expiration dates of the liquid controls.
5. Expected ranges for the low and high liquid controls from the package insert.
6. The microcuvettes lot number, date opened and manufacturer's expiration date. If a second bottle/vial is opened, record the required information next to Cuvette #2.
7. Date(s) the QC testing is done.
8. Results of each low and high liquid control, a pass/fail based on the expected range, and initials of staff performing test, (indicate which cuvette bottle was used for the test).

9. Corrective actions should be recorded in the System Maintenance table at the bottom of log. Record the date, problem/error code, corrective action and staff initials when an error code appears on the analyzer or when a liquid control result fails.
10. Site coordinator (lab director or WIC coordinator) signature and monthly date reviewed.

C. MI-WIC Laboratory Screen

1. All test results (including retests) must also be recorded in the client's record in MI-WIC (see MI-WIC Policy 2.16, Hematological Risk Determination).

D. Record Retention

1. Retain a copy of the manufacturer's package insert for each lot number of liquid control solutions with the corresponding QC logs. The expected ranges of the controls should match the lot number and expected ranges entered on the QC log.
2. Client and QC logs must be maintained according to WIC record retention requirements (see MI-WIC Policy 1.06, Record Retention and Destruction) and be made available for auditing purposes.

E. Quality Assurance

Monitoring data on the QC log may identify faulty equipment and/or errors in technique when capillary sampling is performed. QC logs must be reviewed monthly. The site coordinator and/or laboratory director's signature and date verify the following**:**

1. QC testing was conducted.
2. All documentation on the QC log was complete.
3. Appropriate corrective actions were taken when results were outside expected ranges.

V. Instructions for Client Testing

A. Capillary Blood Sampling

1. Supplies needed for both finger and heel stick:
    a. Gloves (disposable vinyl, nitrile and/or latex gloves)
    b. Alcohol or alcohol prep pads (do not use cotton balls)
    c. Gauze squares or lint-free tissues (Kimwipes)
    d. Lancet for finger puncture, capable of making a puncture at least a depth of 1.5 mm
    e. 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)
    f. Puncture resistant sharps container
    g. Disinfectant, such as freshly prepared 10% household bleach, for work surfaces
    h. Drape tissue paper on which to set testing supplies
    i. Other optional personal protective equipment, e.g., lab coat or scrubs, eye protection. **NOTE**: If a drop of blood gets on clothes, that article of clothing should be soaked in bleach

2. Specimen collection:
   a. Blood should be collected from the finger of adults and children one year and older.
   b. 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.

3. Procedure for finger stick specimen
   a. Ask the client or responsible adult if the client has a bleeding disorder or other medical condition that would contraindicate testing (i.e. hemophilia, fragile bone disease (osteogenesis imperfecta) or serious skin disease). If using latex gloves or other items containing latex (i.e. bandages, medical adhesive tape, or gauze), ask if there is a known allergy to latex. If allergy exists, non-latex gloves, bandages and adhesive tape must be used.
   b. Position the client in a chair suitable for capillary puncture. If the client is a child, instruct the parent how best to support the child to restrain excessive movement.
   c. Clean your hands with hand sanitizer/rub or warm soapy water and dry. Apply gloves.
   d. Ask adult, prior to sampling, if the child sucks his/her fingers. If so, identify which fingers and avoid using them for sampling.
   e. If the client's fingers are cold, place hand under the client's arm.
   f. Remove a HemoCue Hb 301 microcuvette from the vial and recap the vial immediately.
   g. Select an appropriate puncture site (Figure 1). For best results, use the middle finger or the ring finger for sampling. Avoid fingers with rings, scar tissue or callouses. Do not puncture too close to the nail bed. The Clinical Laboratory and Standards Institute (CLSI) does not recommend obtaining a specimen from the ear lobe or toe.

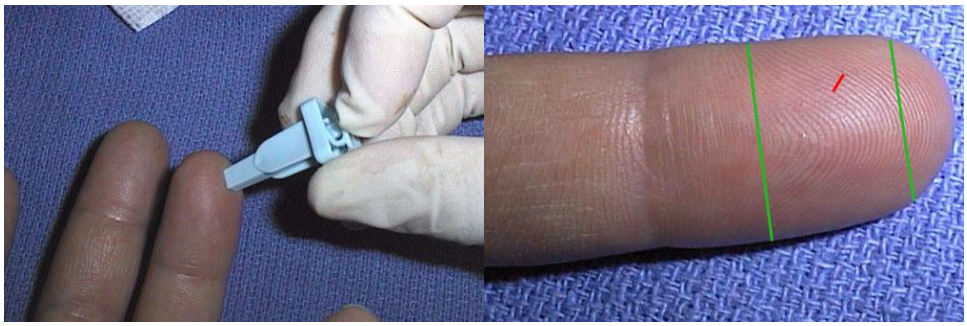

Figure 1

   h. Clean site for blood collection with 70% isopropyl alcohol-soaked gauze or a newly opened alcohol prep pad. Allow the skin to air-dry or dry with gauze or Kimwipe, as wet alcohol on the skin can cause stinging, may dilute the sample, or cause rapid hemolysis (excessive breakdown of red blood cells).
   i. Using your thumb, lightly press the finger from the distal knuckle

(phalanx) to the end of the finger to stimulate blood flow to the sampling point.

j. Perform finger puncture perpendicular to the fingerprint ridges, this will help the blood bead into a large drop. Perform finger puncture using a sterile, single-use retractable, disposable lancet. Press the lancet firmly off center on the fingertip and activate the lancet. Make a deep puncture (1.5 mm) at the chosen site (Figure 1). 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.*
k. Discard the lancet in an approved sharps container.
l. Wipe away the first two large drops of blood. This stimulates the blood flow and lessens the likelihood of a dilution effect by interstitial fluid. If necessary, apply light pressure again, until another drop of blood appears. Avoid “milking of the finger.”
m. Make sure the third drop of blood is big enough to fill the microcuvette completely. Introduce the cuvette tip into the middle of the drop of blood. Keep the cuvette in contact with the drop of blood until filled using one continuous process. Do not refill a partially filled microcuvette.
n. 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.
o. 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.
p. Place the filled microcuvette into the analyzer’s cuvette holder and gently tap the holder into the measuring position and door will automatically close. Filled microcuvettes are to be kept in the horizontal position. The microcuvette must be analyzed within **40 seconds** after being filled.
q. The Hgb value will be displayed in grams/dL within **3 seconds**.
r. Record the result on the WIC Client Log before removing the microcuvette from the instrument.
s. Pull the microcuvette holder out to the loading position. Remove the microcuvette and discard it into a sharps container.
t. Apply a piece of gauze to the puncture site, using slight pressure until the bleeding stops. For older children and adults, offer an adhesive bandage (non-latex preferred). 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 and suggest that the adhesive bandage be removed before leaving the clinic.
u. Remove gloves and clean hands with hand sanitizer/rub or soap and water.

4. Procedure for Heel Stick

a. 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.
b. Thoroughly clean your hands with hand sanitizer/rub or warm soapy water and dry. Apply gloves.
c. Clean the infant's heel with 70% isopropyl alcohol. Allow the heel to air dry or dry with gauze or Kimwipe, as wet alcohol on the skin can cause stinging, may dilute the sample, or cause rapid hemolysis (excessive breakdown of red blood cells).
d. Using a lancet or heel incision device, perform the puncture on the plantar surface of the heel (shaded area Figure 2). 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 2). CLSI does not recommend obtaining a specimen from the toe.

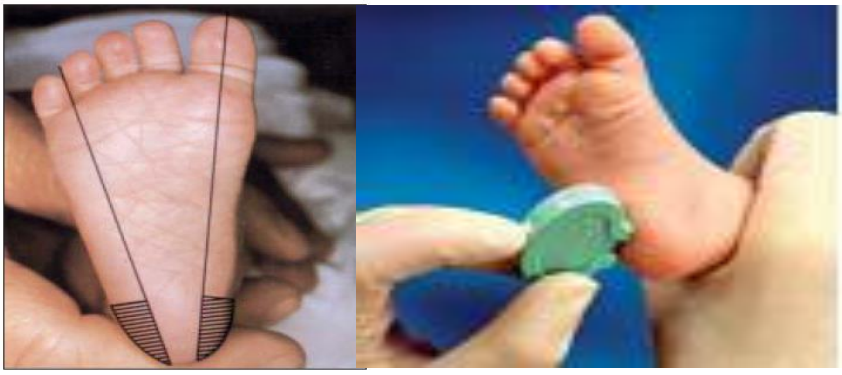

Figure 2

e. 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.
f. 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.*
g. Make sure the third drop of blood is big enough to fill the microcuvette completely. Introduce the cuvette tip into the middle of the drop of blood. Keep the cuvette in contact with the drop of blood until filled using one continuous process. Do not refill a partially filled microcuvette.
h. 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.
i. 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.
j. Place the filled microcuvette into the analyzer's cuvette holder and

gently tap the holder into the measuring position and door will automatically close. Filled microcuvettes are to be kept in the horizontal position. The microcuvette must be analyzed within **40 seconds** after being filled.

k. The Hgb value will be displayed in grams/dL within **3 seconds**.
l. Record the result on the WIC Client Log before removing the microcuvette from the instrument.
m. Pull the microcuvette holder out to the loading position. Remove the microcuvette and discard into sharps container.
n. 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.
o. Remove gloves and thoroughly clean your hands with hand sanitizer/rub or warm soapy water.

VI. Analyzer Cleaning Schedule

A. Remove and clean the microcuvette holder at the end of each day testing is performed. It should be cleaned with 70% isopropyl alcohol or a mild soap solution. Air dry before reinserting (about 15 minutes).
B. Clean the exterior of the HemoCue instrument daily with alcohol or a mild soap solution (never use abrasives).
C. Clean the interior of the analyzer only if/when an error code appears (see Appendix D: HemoCue Hb 301 Operating Manual).
D. For more information, see the HemoCue Hb 301 Operating Manual, Maintenance section.

References

a. Centers for Disease Control and Prevention. “Bloodborne Infectious Diseases: HIV/AIDS, Hepatitis B, Hepatitis C." The National Institute for Occupational Safety and Health/Workplace Safety & Health Topics. Web. 06 September 2016. <https://www.cdc.gov/niosh/topics/bbp/>.

b. Centers for Disease Control and Prevention. Guide to Infection Prevention for Outpatient Settings: Minimum expectations for Safe Care. Centers for Disease Control. Web. Version 2.3. September 2016. <https://www.cdc.gov/infectioncontrol/pdf/outpatient/guide.pdf>.

c. Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/ IDSA Hand Hygiene Task Force. MMWR 2002; 51(No. RR-16 <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>.

d. Centers for Disease Control and Prevention. “Hand Hygiene in Healthcare Settings.” Centers for Disease Control. Web. 25 June 2018 <www.cdc.gov/handhygiene/providers/index.html>.

e. Centers for Disease Control and Prevention, Recommendations to Prevent and Control Iron Deficiency in the United States, MMWR, April 3, 1998/47 (RR-3); 1-36. <https://www.cdc.gov/mmwr/pdf/rr/rr4703.pdf>

f. Clinical Laboratory Improvement Amendments (CLIA). <https://www.michigan.gov/lara/0,4601,7-154-89334_63294_72971_78688---,00.html>.

g. Clinical Laboratory Improvement Amendments (CLIA) Application: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>.

h. Clinical Laboratory and Standards Institute (CLSI). *Blood Collection on Filter Paper for Newborn Screening Programs* NBS01 – A6*.* Vol. 33. No. 9. Approved Standard Sixth-Edition, ISBN 1-56238-883-5 (Print), ISBN 1-56238-884-9 (Electronic). Wayne, PA. Clinical Laboratory Standards Institute; July 2013. **<**https://www.clsi.org/standards/products/newborn-screening/documents/nbs01/**>**

i. Clinical Laboratory and Standards Institute (CLSI). Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Sixth Edition. CLSI document GP42-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2008. <https://www.clsi.org/standards/products/general-laboratory/documents/gp42/>

j. HemoCue Hb 301 Operating Manual. HemoCue, Inc. 250 South Kraemer Boulevard, Brea, CA 92821. Phone: 800-881-1611. <https://www.cliawaived.com/web/items/pdf/HMC-HB1PROMO%20PI~5136file3.pdf>

k. List D: EPA’s Registered Antimicrobial Products Effective Against Human HIV-1 and Hepatitis B Virus. Selected EPA-registered Disinfectants. U.S. Environmental Protection Agency. 04 January 2018. Chemical Safety and Office of Pollution. Washington D.C. 20460

<https://www.epa.gov/pesticide-registration/list-d-epas-registered-antimicrobial-products-effective-against-human-hiv-1>.

l. List F: EPA's Registered Antimicrobial Products Effective Against Hepatitis C Virus. U. S. Environmental Protection Agency. 05 January 2018. Office of Pesticide Programs. Washington D.C. 20460. <https://www.epa.gov/sites/production/files/2018-01/documents/2018.05.01.listf_.pdf > and <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants >.

m. Michigan Department of Environment, Great Lakes, and Energy. Medical Waste Regulatory Act, part 138 of Public Health Code, 1978 PA 369 as amended. <https://www.michigan.gov/statelicensesearch/0,4671,7-180-24786-245023--,00.html>

n. National Academy of Medicine, (Institute of Medicine, 1996). WIC Nutrition Risk Criteria: A Scientific Assessment. pp.154-159. Washington, D.C. National Academy Press. < http://www.fns.usda.gov/sites/default/files/WICDietaryRisk.pdf>.

o. Specimen Collection: Blood Collection by Finger Puncture and Heel Stick, R.L.04.02, Michigan Regional Laboratory System, May 2008. <https://www.phlebotomycareertraining.com/wp-content/uploads/2012/02/Specimen_Collection_Blood_by_Finger_Puncture.pdf>

p. State of Michigan, Department of Licensing and Regulatory Affairs, Occupational Health Standards. MIOSHA-STD-1209 (10/15). Web. 27 February 2012 <http://www.michigan.gov/documents/CIS_WSH_part554_35632_7.pdf>.

q. Thorn, B., Kline, N., Tadler, C., Budge, E., Wilcox-Cook, E., Michaels, J., Mendelson, M., Patlan, K. L., & Tran, V. (2018). WIC Participant and Program Characteristics 2016. Alexandria, VA: U.S. Department of Agriculture, Food and Nutrition Service. < https://fns-prod.azureedge.net/sites/default/files/ops/WICPC2016.pdf>

r. WHO. The global prevalence of anaemia in 2011. Geneva: World Health Organization; 2015. <https://apps.who.int/iris/bitstream/handle/10665/177094/9789241564960_eng.pdf;sequence=1>

s. Standard Precautions: < https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html>

t. Federal Regulations Laboratory Requirements: <https://www.ecfr.gov/cgi-bin/text-idx?SID=f64897dadaac9e8f2a27d57b888ad194&mc=true&node=pt42.5.493&rgn=div5> >

u. Medical Waste Directory <https://www.michigan.gov/documents/deq/deq-rmd-mwrp-medical-waste-directory_350137_7.pdf>

Cross Reference:

MI WIC Policy 1.03 Confidentiality
MI WIC Policy 1.06 Record Retention and Destruction
MI WIC Policy 2.16 Hematological Risk Determination
MI WIC Policy 2.18A Michigan WIC Client Agreement