

**ARIZONA DEPARTMENT OF
HEALTH SERVICES**

**BUREAU OF NUTRITION &
PHYSICAL ACTIVITY**



LABORATORY PROCEDURE MANUAL

6th Edition
2009

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Chapter 1. Introduction

Purpose The purpose of the Arizona Department of Health Services, Bureau of Nutrition & Physical Activity Laboratory Procedure Manual is to provide guidance to local agency staff while performing hemoglobin tests used in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), the Commodity Supplemental Food Program (CSFP) and the Community Nutrition Programs. The manual is designed to be user-friendly.

Effective January 1, 2010, the Arizona WIC Program has transitioned to the HemoCue® 201+ analyzers. HemoCue® 201+ analyzers require a small blood sample size, do not track or store data, and have an internal electronic self-test. The self-test verifies the performance of the optronic unit and is performed every second hour that the machine is on.

Here is what you will find in the revised sixth edition of the lab manual:

Training Local Agencies have the option to designate a Local Agency trainer who, after becoming certified by ADHS Bureau of Nutrition & Physical Activity, can act as the Agency's trainer for new & existing staff. They must also undergo yearly reevaluation by ADHS BNPA to ensure their competency.

New staff members will be monitored quarterly for their first year. Subsequently, all appropriate WIC staff will undergo mandatory monitoring every 2 years and continuous monitoring throughout the year.

Administration of HemoCue® Equipment This section includes procedures for receipt and inventory of new or loaner equipment from ADHS or directly from HemoCue®.

Problems With An Analyzer This section explains the HemoCue® 201+ System Maintenance Log to record relevant information in the event of problems with an analyzer.

Chapter 2. Safety

Universal Precautions

In 1991, the Occupational Safety and Health Administration (OSHA) published the Occupational Exposure to Bloodborne Pathogens Standard. The purpose of the standard is to minimize, if not eliminate, occupational exposure to bloodborne pathogens and, if followed, should keep you safe when you work in your lab area. The standard outlines necessary engineering and work practice controls, as well as requiring the availability and use of personal protective equipment (PPE).

One section of the standard deals with "Universal Precautions (UP)." This term is simply an approach or strategy designed to keep you safe when you work with blood or other bodily fluids. Under UP, the blood and certain bodily fluids of *all* individuals are considered potentially infectious. Standardized practices focus on treating every sample of blood as if it were disease-infected. Handle all human blood and certain human bodily fluids as if they were known to be infected with Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or other bloodborne pathogens. Ask your supervisor if you have further questions.

These precautions are intended to prevent the transmission of infectious bodily fluids through parenteral routes such as mucous membranes and non-intact skin.

In 2001, the standard was revised to conform to the Needlestick Safety and Prevention Act. The act directed OSHA to revise the Bloodborne Pathogens (BBP) Standard in the areas of the Exposure Control Plan with new record-keeping requirements, employee input for work practice controls and modification of definitions of engineering controls.

Personal Work Practices

To comply with the OSHA standard, a written exposure control plan must be in place at each WIC clinic/site. The plan includes a copy of local policies and procedures for employee safety and a procedure for reporting accidents. Your manual should be kept close at hand and you should adhere to all of the practices as suggested in this manual. Each local agency will develop blood-borne pathogen information and training programs for all employees.

For your personal protection, follow these guidelines:

- Get a Hepatitis B vaccination.
 - Do not allow or bring food, drinks or medication into technical work areas.
 - Do not touch your face, apply makeup or handle contact lenses while in work areas where there is a reasonable likelihood of occupational exposure.
 - Food and drink shall not be kept in refrigerators, freezers, shelves or on countertops where blood or other potentially infectious materials are present.
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Safety Continued

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| Personal Work Practices Continued | <ul style="list-style-type: none">• The single most important means of preventing the spread of infection is handwashing. Wash your hands:<ul style="list-style-type: none">✓ At the beginning and end of your shift✓ Before a skin puncture and after removing your gloves✓ After weighing unclothed infants✓ After touching contaminated objects or using restroom facilities✓ After making contact with your eyes, nose or mouth✓ Before and after eating, drinking or handling food• Cover any break in the skin with a bandage.• Wear disposable gloves when there is a possibility of contact with bloodborne pathogens.• Use new gloves for every blood draw, even if participants are from the same family.• Take advantage of all training offered by your employer. Your employer has considered the risks of contamination and established its own standards based on "reasonable risk."• <u>Note</u>: Your local agency may determine whether masks, eye protection devices such as goggles or glasses with solid side shields, or chin length face shields, should be worn.• Usually, protective devices for eyes, nose or mouth are worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and contamination may be anticipated. It is generally accepted that the HemoCue® test for hemoglobin does not splatter or spray blood. |
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Warning!
If blood touches your skin or hair, wash the area with soap and water, and tell your supervisor immediately.

If blood splashes into your eyes, flush them with water. Contact a physician.

If you are accidentally stuck by a contaminated lancet, contact your supervisor. Arrange to see a licensed healthcare provider for a medical evaluation and counseling and to be tested for Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).

Safety Continued

Worksite Protection

- Recommended Lancet for Finger Punctures (children >18 months and adults): Single-Use (needle is not able to be extended a second time) Capillary Blood Sampling Device, 2.25mm needle.
- Recommended Lancet for Heel Punctures (**infants 9-18 months and children with very small fingers**): Single-Use Capillary Blood Sampling Device, 1.8mm needle.
- Clean the work site at the beginning and end of each workday or after any contact with blood or other potentially infectious materials.
- Use a prepared bleach solution (see below) or an EPA-registered disinfectant that is effective as a tuberculocidal and kills Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).
- In order to decontaminate contaminated work surfaces. Be sure to:
 - 1) Wear clean gloves
 - 2) Completely remove all blood before applying the disinfectant
 - 3) Leave the surface wet with the disinfectant for 30 seconds for HIV and 10 minutes for HBV
 - 4) Dispose of the infectious waste in accordance with federal, state, or local regulations (see page seven)
- EPA-registered tuberculocidal disinfectants and bleach solutions are appropriate for removing blood or other potentially infectious materials on surfaces and instruments. The Material Safety Data Sheet (MSDS) for commercial disinfectants must be posted in the clinic and all employees must be aware of its location.

Preparation and Storage of Bleach Solution

- Prepare a fresh bleach (5.25% sodium hypochlorite) solution weekly.
 - To prepare a 10% bleach solution, mix 1 part household bleach with 9 parts tap water.
 - Store at room temperature in an opaque plastic bottle labeled "10% Bleach." The date of preparation and the expiration date should be clearly marked on the outside.
Note: The expiration date is at the end of the seventh calendar day.
 - Store out of the reach of children.
-

Safety Continued

Disposal of Laboratory Waste and Supplies



- Discard all contaminated sharps, i.e.: retractable lancets & cuvettes, in special receptacles usually referred to as “sharps” containers. There are a variety of styles, and all are clearly marked with a biohazard symbol (see figure to the left). The container must be rigid, puncture-resistant, leak-proof, and disposable with a locking lid.
 - Regardless of whether or not lancets contain safety features, such as retractable blades, all used lancets and other sharp objects must be disposed of immediately in a “sharps” container. When this container is filled to the acceptable level, it must be properly disposed of as biohazardous waste.
 - Throw away other potentially infectious trash that is saturated with blood in a red, plastic biohazard bag. Find out from your supervisor how to handle biohazardous waste since it must be decontaminated before it can be disposed of in a landfill.
 - All waste that is saturated and dripping with blood must be
 - ✓ Sterilized
 - ✓ Incinerated or
 - ✓ Chemically disinfected prior to mixing and disposing with ordinary waste.
 - Waste, such as lint-free tissue, alcohol preps, gloves, bandages & wrappers, that contains blood but is not dripping, can be discarded in a regular trash bag if there are no means for biohazard waste disposal. Best Practice states it should be disposed of in a biohazard bag.
 - Keep the biohazard bag and all trash out of the reach of children.
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Chapter 3. Information About Blood Testing

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| Type of Blood Tests | There are many components of blood, and many tests are done for diagnostic purposes. The only blood test that will be addressed in this manual is hemoglobin. |
| Hemoglobin Testing | WIC staff conduct hemoglobin tests to screen and assess the participant's nutritional status. The test measures the amount of hemoglobin in the red blood cells. The hemoglobin test is performed because it is a quick screening tool for iron deficiency anemia. |
| Anemia | A low hemoglobin test result indicates the possibility of iron deficiency anemia. Anemia is a condition in which there are low levels of iron in the blood, with symptoms such as poor appetite, tiredness, weakness, developmental delays and learning problems present. It is the most prevalent risk factor of WIC participants. In the WIC program, a low hemoglobin level is most often treated with education and foods high in iron and Vitamin C. Referral for high-risk counseling and medical treatment may also be indicated. (Appendix A) |
| Anemia Cutoffs | Arizona uses the 1998 Centers for Disease Control and Prevention (CDC) Guidelines for anemia cutoffs (Appendix B). These cutoffs are also recommended by the Institute of Medicine as an acceptable reference. The cut-off values for anemia vary with altitude, age, sex, smoking status and stage of pregnancy. |
| Correct Values | You, as a health professional/paraprofessional, have an important responsibility for correctly assessing values which may determine whether or not a person is eligible for the WIC Program. The values also determine the type of counseling and referral a participant receives. |
| Training | The Local Agency Director or designated Local Agency trainer is responsible for ensuring the training, monitoring and supervision of the staff members who perform laboratory collection and analysis. Training must be adequate to meet the Clinical Laboratory Improvement Amendments (CLIA '88) regulations & follow the National Committee for Clinical Laboratory Standards (NCCLS) H4-A4 guidelines. The designated trainer must be certified and reevaluated yearly by ADHS Bureau of Nutrition & Physical Activity to ensure competency. |

Information about Blood Testing Continued

Laboratory Certification

The Local Agency Director is responsible for obtaining and maintaining a Certificate of Waiver in accordance with Clinical Laboratory Improvement Amendment (CLIA) regulations. Applications can be downloaded from the Arizona Department of Health Services Website (<http://www.azdhs.gov/lab/license/cli.htm>).

- Follow the link labeled: **Applications**
- Click on: **Certificate of Waiver or Certificate of PPMP [PDF 5M]**
- Print and complete the application
- Send the completed application to:

Office of Laboratory Services

ATTN: CLIA

250 N. 17th Avenue

Phoenix, AZ 85007

Or fax to (602) 364-0759

Once the application is received and processed, an invoice will be sent to the local agency from the CMS (Center for Medicare and Medicaid Services) Program at the federal level. This invoice will state an official CLIA number and a fee amount. The agency must send payment for the said fee to CMS at the address stated on the invoice. Checks must be made out to CMS Laboratory Program and include the CLIA number.

The agency must obtain a valid certificate before performing any laboratory screening tests and must maintain a valid certificate at all times. The certificate is valid for two years, and the agency is responsible for applying for certificate renewal before their current certificate expires.

Authorization

A Letter of Authorization, which lists the individuals qualified to obtain and analyze laboratory samples, as well as the dates when they were certified, will be maintained on file by each local agency. The letter also needs to contain dates for which certification is valid (i.e.: October 1, 20XX - September 30, 20XX).

Questions regarding CLIA certifications and Letters of Authorization can be directed to **Tanja James** at jamest@azdhs.gov or by phone at **602-364-0139**.

Information about Blood Testing Continued

Work Area

Select a work area for collection of the laboratory specimen.

An ideal work area:

- Is clean
 - Ensures client and staff safety
 - Has a surface which is smooth, free of cracks, and washable
 - Ensures patient privacy
 - Is away from noise and confusion
 - Has a chair and table
-

Hemoglobin Measuring Machines



HB 201+

The HemoCue® 201+ system is an analyzer, a portable instrument with a sliding cuvette holder and display screen. The analyzer measures the amount of hemoglobin contained in a blood sample. The measurement takes up to 60 seconds and is expressed as grams per deciliter or g/dl. After reading the sample, the value will remain displayed on the screen as long as the cuvette holder is in the measuring position. When a new sample is placed in the cuvette holder, the analyzer erases the previous value and replaces it with the new value.

The analyzer operates on AC power (AC adapter included) or 4 AA batteries. The battery symbol on the display indicates low battery power; if showing, replace the batteries as soon as possible.

Daily care of the hemoglobin analyzer is explained in Chapter 6 of this manual. Detailed cleaning instructions are also found in the HemoCue Hb 201+ Analyzer Operating Manual.

Storage of Cuvettes

- Store cuvettes at room temperature. Do not expose to any direct heat source.
 - Label the vial with the date on which it is opened.
 - Label the vial with the date on which the contents of the vial expire (vial expires 90 days after opening). Note: an unopened vial of cuvettes has a two-year shelf life from the date of manufacture.
 - Snap the vial cap closed each time a cuvette is removed. Never leave the cap partially open. The cuvettes are very sensitive to humidity and moisture. Remove one cuvette at a time for testing.
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Chapter 4. Daily Steps for Performing Hemoglobin Tests

Identify Client Assure that the consent boxes are checked and the client or authorized representative has signed and dated the Rights & Obligations form.

Explain Procedure Explain the procedure to the client or authorized representative in simple terms. Reassure them.

Example

"I am going to make a little poke in your finger/heel to get a few drops of blood to put the blood into this little container. Then I am going to put it into this machine to find out how much iron it has in it." Be honest with him/her. If he/she asks if it may hurt, answer, "Yes, it may hurt a little."

Don't ever say, "No, it won't hurt."

Cleanse/Glove Hands Wash hands with soap and water (or cleanse with an alcohol-based hand cleanser or hand wipes if a sink is not available). You may wait until after supplies are assembled to put on gloves.

CHANGE GLOVES BETWEEN EVERY CLIENT!

Assemble Supplies Hands must be clean before assembling supplies. They may also be gloved if desired.

- HemoCue® Analyzer
- Gloves
- Alcohol prep pads
- Sterile lancets
- Lint-free tissues/KimWipes® or Gauze pad
- Closed vial of cuvettes (remove 1 at a time & recap)
- Bandages (not for children under age 2)
- Sharps container
- Biohazard bag
- 10% bleach solution or disinfectant
- Soap and water, alcohol-based hand cleanser or hand wipes

Put gloves on after supplies are assembled if you haven't already done so.

Daily Steps for Performing Hemoglobin Tests Continued

Position Client

For infants one year of age and younger, a seated adult holds the infant over adult's shoulder or baby lies face-down across lap for heelstick.

NOTE: The heel site is recommended for infants 9-12 months of age to prevent possible bone or nerve damage in areas where there is less flesh. If a child 12-18 months of age has small fingers, it is at the staff's discretion to continue with a heelstick or to use a smaller lancet on their finger. Children 18 months of age and older should not receive a heelstick.

For everyone else, seat client and extend arm with palm up.

♥ BE SURE THAT PUNCTURE SITE IS LOWER THAN THE HEART.

Choose Site

For infants, use either side of the plantar (bottom) surface of the heel when the baby is held over caregiver's shoulder. Never puncture the back curvature of the heel.

For everyone else, seat the participant or ask someone to help with a child. For instance, the caregiver may hold the child in his/her lap using both arms to keep the child still while you perform the procedure.

Have the client extend his/her arm with the hand lower than the heart and palm facing up. Use the middle or ring finger, but choose a finger that doesn't have a ring on it.

Warm the Site (If Necessary)

The site should not be cold, blue, swollen or calloused.

If cold, warm the site by holding it in your hands, rubbing it for a minute, or by having the participant wash their hands vigorously with warm running water and soap or gently shake her hands. The site does not need to be cleaned again with an alcohol pad.

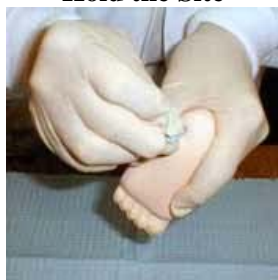
Cleanse the Site

Cleanse the site thoroughly with an alcohol pad (unless the participant washed their hands with warm water and soap).

Wipe the site with a tissue or lint-free wipe. Be sure skin is *dry*.

Note: Pooled alcohol at the puncture site will dilute and hemolyze the blood, giving a lower reading, if the skin surface is not dried completely.

Hold the Site



For infants, position the foot below the infant's heart. Encircle the heel by wrapping the index finger around the arch and the thumb around the bottom of the heel (see figure to the left). Grasp the heel or finger firmly between your thumb and index finger using your thumb in a gentle rocking movement.

For everyone else, lightly press the finger from the closest knuckle to the tip in a rolling motion to stimulate the flow of blood to the sampling point.

WHAT NOT TO DO:

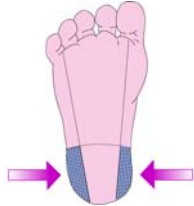
Do not touch the prepared site after cleaning. Do not "milk" the finger to speed the process. Squeezing/milking dilutes the blood and gives a false low reading.

Daily Steps for Performing Hemoglobin Tests Continued

Puncture

IMPORTANT:

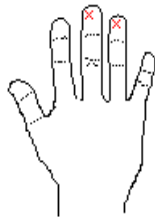
If the lancet is blade-shaped, it should be placed perpendicularly to the whorls of the fingerprint/footprint so the blood is more easily collected into the cuvette.



Create a firm surface where you are going to puncture by pulling the skin taut or tight with your index finger near the first joint of the finger on the client's hand.

For infants, 9-18 months of age or children with very small fingers, puncture only on the medial or lateral side of the bottom surface of the heel. See figure to the left.

Do not puncture the foot if there are bruises, abrasions or sloughing skin present.



For everyone else, children > 18 months of age and adults, puncture the side of the fingerpad nearest the thumb in one continuous motion using a retractable lancet. This will allow for easy blood collection. Puncturing on the side of the fingerpad is recommended and will hurt less than on top of the fingerpad since there are less nerve endings. The finger should be facing upwards upon puncture.

Fill the Cuvette



To ensure accuracy, you must wipe away the first two to three drops of blood. This will stimulate spontaneous blood flow, resulting in a better sample. If necessary, press gently again with thumb and forefinger until another drop of blood appears. Avoid "milking." **Do not touch the heel or finger at the site of puncture.**

All drops should be large enough so they "sit" on top of the heel or finger like a bead. Ensure that the drop of blood is big enough to **fill the entire cuvette, including the tip**. Touch the tip of the cuvette, pointing downward, into the middle of the blood drop so the cuvette touches the skin. Allow the cuvette to fill in one step. The cuvette will fill itself automatically. Never "top off" the cuvette if it doesn't fill in the first swipe.

Daily Steps for Performing Hemoglobin Tests Continued

Fill the Cuvette Continued Wipe excess blood off the flat outside surfaces of the cuvette. Keep it at a 45° angle. Be careful not to touch the open-ended tip so that blood is not pulled back out of the cuvette.

Example

Using a gauze pad or lint-free wipe, "swipe" the cuvette as if you were sharpening a knife to remove any excess blood from the outside surfaces. Avoid the open "slit" of the cuvette with the gauze or wipe.

If the cuvette does not fill completely on the first try, or if air bubbles are visible, discard the cuvette, wipe the puncture site and allow a new, larger bead of blood to form before collecting into the cuvette again.

Measuring Hemoglobin Value

Pull the cuvette holder out to loading position. Turn the analyzer on by pressing and holding the On/Off button until the display is activated. The machine will run a self-test and then display three flashing dashes.

Within 10 minutes of filling the cuvette, place it in its holder and gently push the holder into the analyzer with two fingers. When closed, the analyzer will automatically start the measuring procedure and the result will appear on the display within 15-60 seconds.

Seal and Bandage Site

Place dry gauze or lint-free tissue over the puncture site and apply gentle pressure until the wound is clotted. Elevating the hand or foot above the level of the heart will help to stop the blood flow. Apply the bandage.

Note: Do not use bandages on the finger of a child less than two years of age to prevent potential ingestion and choking.

When to Run a Second Test

Occasionally, a second test must be run, such as when the displayed hemoglobin value is outside the "Nutritionist" range (Appendix B). A second sample must be taken from a different site, preferably a finger on the other hand and/or by a different user. The higher of the two hemoglobin values is entered into the AIM computer system and should also be used for referral purposes.

Example

A 6.9 g/dl reading is obtained from an 18-month-old. The second reading is 8.5 g/dl. Record 8.5 g/dl, counsel and write this higher value on the referral form to the medical provider.

Daily Steps for Performing Hemoglobin Tests Continued

Very low hemoglobin values

A very low hemoglobin level is a serious medical concern and is life-threatening. Local Agencies must establish a referral plan and train staff to ensure that all participants with confirmed very low hemoglobin values are referred for an immediate medical evaluation, either with their primary care provider or, if unavailable, at an emergency medical center. Local Agencies will work with county/agency Health Program Officers to determine clinic referral procedures. All referrals must be documented in AIM.

See Appendix A for the table of very low hemoglobin levels.

Cleanse Surface

If any blood spills on the HemoCue® Analyzer, work surfaces or skin, clean with a 10% bleach solution or disinfectant spray immediately.

Disposal of Supplies

- Throw away any paper wrappers, alcohol preps, gauze, lint-free tissues, gloves and other supplies which are not saturated and dripping with blood in a wastebasket.
 - Throw away any supplies that are saturated and dripping with blood in the red biohazard bag. If your gloves are contaminated with blood, turn the gloves inside out while taking them off and place in the biohazard bag with the other supplies.
 - Throw away all lancets and used cuvettes in the sharps container.
-

Remove Gloves and Wash Hands

Remove and discard gloves after each client and after handling contaminated waste. Clean hands with soap and water, alcohol-based hand cleanser or hand wipes if water is not available. Antiseptic hand cleanser, in conjunction with clean cloth/paper towels or antiseptic towelettes, are examples of acceptable alternatives to running water. However, when these types of alternatives are used, employees should wash their hands (or other affected areas) with soap and running water as soon as possible.

Daily Steps for Performing Hemoglobin Tests Continued

**Factors
Responsible
for Poor
Results**

Mechanical problems such as:

- Malfunctioning equipment
- Machine not clean
- Cuvettes past expiration date or left exposed to air

Poor collection technique, such as:

- Not thoroughly drying the site prior to puncture
 - Milking the site
 - Not wiping away the first two to three drops of blood
 - "Topping off" the cuvette with additional blood, resulting in air bubbles or layers in the cuvette
 - Not filling the cuvette entirely
 - Leaving the filled cuvette out of hemoglobin machine more than 10 minutes before measuring
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Chapter 5. Staff Evaluation

Policy

All staff members performing blood tests will be trained at ADHS Bureau of Nutrition & Physical Activity as a minimum requirement and authorized as competent before they perform any patient/client testing. They may also receive training at the local agency by the laboratory director or the Local Agency's designated trainer that has been certified by ADHS Bureau of Nutrition & Physical Activity.

New staff members who are authorized to perform blood testing will be monitored quarterly for their first year. Subsequently, all appropriate WIC staff will undergo mandatory monitoring every 2 years by the laboratory director or the Local Agency's designated trainer on capillary techniques and use of the HemoCue® equipment. The Staff Competency Check List will be used for monitoring (Appendix C). Continuous monitoring should also be done to ensure proper implementation of the policies and procedures regarding blood collection, analysis, and quality assurance.

Staff training will be documented in the Learning Management System (LMS).

Procedure

For agencies that have local agency-provided training, the following procedure is suggested:

1. The laboratory director or designee will observe each staff member performing each step of collection procedures as outlined on the Staff Competency Check List, Appendix C.
 2. The steps must be performed in an initial and follow-up practice session prior to clinical practice.
 3. When a step has been completed correctly, the supervisor will place a check mark (√) in the appropriate box.
 4. When a rating of 100% is obtained, the staff member is re-evaluated in two weeks. If a rating of 100% is not obtained, the staff member will be re-evaluated at one-week intervals until the 100% rating has been obtained.
 5. Two consecutive ratings of 100% should be attained prior to authorization to perform patient/client testing.
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Chapter 6. Administration & Maintenance of HemoCue® Equipment for the Local Agencies

Equipment All analyzers and cuvettes will be provided through ADHS. Purchase of lancets are the responsibility of the local agency. See chapter two for recommended lancet sizes.

Inventory Control - Equipment Returns or Replacements The Local Agency administration or HemoCue® Lead will maintain current inventory of existing analyzers at all clinics, including backup equipment not in use. Inventory should include a minimum of serial numbers and corresponding site locations. This will include any loaner equipment received from HemoCue® during repairs. Any changes in inventory will be immediately reported to the State office.

Each Local Agency will have a minimum of one spare analyzer on hand at all times. Some agencies will have more spares available based on their size. A small par of analyzers will also be available in the State BNPA warehouse for immediate needs.

Quality Control When the analyzer is turned on, it will perform a self-test. The self-test verifies the performance of the optronic unit and is performed every second hour that the machine is on. If the self-test fails, see Maintenance section below. There is no need to perform other quality control tests, unless required by your Local Agency.

Maintenance of the Analyzer Analyzers should be cleaned to resolve certain error codes and as needed. See the Trouble Shooting Guide in Appendix F. Local Agencies will develop policies for maintaining cleanliness of the analyzer. Cleaning instructions can also be found in the HemoCue® Hb 201+ Operating Manual.
NOTE: When the Operating Manual states to clean the analyzer/cuvette holder with alcohol, it refers to Swedish alcohol, not alcohol sold in the US. Instead of alcohol, use mild soap and water.

The cuvette holder can be cleaned with mild soap and water and left to dry completely before reinserting into the analyzer.

The exterior of the analyzer can be cleaned with mild soap and water.

Chapter 6. Administration & Maintenance of HemoCue® Equipment for the Local Agencies Continued

Chain of Support for Troubleshooting

The following chain of support should be followed when resolving challenges with the Analyzer ONLY AFTER THE ERROR HAS BEEN ADDRESSED WITHOUT RESOLUTION:

1st Contact – Site Supervisor

2nd Contact – Site Supervisor or Local Agency HemoCue Lead will call the state Community Services Team Administrative Assistant to report the problem. The state contact will walk the Local Agency through correcting the problem.

3rd Contact - If the problem requires additional attention the site will be instructed to contact Arizona's personal technical support with HemoCue® at 1-800-881-1611, extension 128. See Appendix D for contact names and phone numbers.

Chapter 7. Problems with the HemoCue[®] Analyzer

System Maintenance Log

The HemoCue[®] Hb 201⁺ System Maintenance Log will be maintained in a notebook in the clinic's lab area. In the event of a problem with the analyzer, all relevant information should be recorded on the Maintenance Log. See Appendix E.

Chapter 8. Glossary

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| Accuracy | The agreement of results with the true value for specimens measured. |
| Anemia | Hemoglobin concentration (or hematocrit) below the 5th percentile of the distribution of hemoglobin or hematocrit of healthy, well-nourished individuals of the same sex, age and stage of pregnancy. |
| Biohazard Bag/Container | A bag or container constructed of material of sufficient single thickness and strength to pass the 165-ram dropped dart impact resistant test as prescribed by STM D-1709-91 and certified by the bag manufacturer (usually red or orange and labeled "Biohazard"). |
| Calibration | A means to determine the accuracy of an instrument by comparing it with a known standard. The HemoCue® Analyzer does a calibration “self-test” each time the analyzer is turned on. |
| CLIA ('88) | Clinical Laboratory Improvement Amendment of 1988 – a public law governing the operation of clinical laboratories in the U.S. and mandating that all laboratories must be regulated using the same standards regardless of the location, type or size. |
| Cuvette | A small transparent container in which solutions are placed for photometric analysis. |
| EPA-registered Disinfectant | A cleanser that is recognized by the Environmental Protection Agency as being effective against tuberculosis-causing bacteria as well as HIV & HBV. It is used to decontaminate work surfaces. |
| Hemoglobin | The main component of red blood cells. It serves as a vehicle for transportation of oxygen to the tissues and carbon dioxide from the tissues to the lungs. |
| Hemolysis | The destruction of red blood cell membrane causing release of hemoglobin into surrounding serum or plasma. |
| Iron Deficiency Anemia | A reduction in the number of red blood cells resulting from iron depletion as evidenced by other laboratory testing. |

Glossary Continued

| | |
|------------------------------|---|
| Lancet | A sharp metal needle or blade, often encased in plastic, which is used to puncture the skin in order to collect a blood sample. It is individually packaged to ensure sterility. OSHA requires it to be retractable or self-sheathing, disposable and used only once. |
| Milking | To press out, drain off, remove, or draw out blood as if by milking. |
| Rocking | A method used to increase blood circulation and flow to the skin puncture site by using a thumb or finger in a gentle rocking movement (lightly press the finger from the knuckle nearest the fingertip toward the end of the finger). |
| Sharps | A medical device or instrument such as a hypodermic needle, syringe, lancet, scalpel blade, cuvette, Pasteur pipette or broken glass that can cause a cut, puncture, or laceration. |
| Universal Precautions | A set of rules established by the CDC, and adopted by OSHA, to control infection from bodily fluids in the health care setting. |
| Standard Precautions | Guidelines that apply to blood, all bodily fluids, non-intact skin and mucous membranes; replace Universal Precautions and are to be used for the care of all patients since everyone is assumed to be infected and, therefore, a possible contaminating factor. |
| Vial | A small container with a lid, used especially for storing liquids. |

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Appendices

Appendix A - Blood Work Requirements, Options and Referrals

Appendix A - Blood Work Requirements, Options and Referrals

Policy 7 CFR §246.7(e)(1) Determination of nutritional risk, and Nutrition Risk Sections of State Plan for Risk 201 for women, infants and children states that "At a minimum, . . . a hematological test for anemia such as hemoglobin...shall be performed and/or documented at certification for applicants with no other nutritional risk present. For applicants with a qualifying nutritional risk factor present at certification, such test shall be performed and/or documented within ninety (90) days of the date of certification."

The Blood Work Rule effective January 18, 2000, states that liberalizing the timeframes of blood collection is based on WIC's track record of reducing anemia rates nationally and improving coordination of services. Arizona WIC recognizes that it has one of the highest rates of anemia nationally and has enthusiastically adopted parts of the blood work rule, which will reduce barriers to service without sacrificing data collection.

Special Note Anemia (blood) screening is part of the WIC certification process (which may be obtained via referral) and is mandatory for participation. The only time blood testing may be waived is if there is a religious objection (i.e. Christian Scientist) or a medical reason (i.e. hemophilia) or if performing the test will cause physical harm to the participant and/or staff member. In this case, one (1) month of Food Instruments may be issued and the blood test will be attempted in one month at their next WIC visit. Thus, a person may not be certified without blood work data except when religious or medical reasons exist and this must be noted in their WIC record.

If blood work data is brought from an outside source within 90 days of certification, the actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being entered into AIM.

Appendix A - Blood Work Requirements, Options and Referrals

| Category | Age Blood Work Required | Certification Blood Work Required | Exceptions to Certification Blood Work Required |
|---------------------------|---|---|--|
| Pregnant women | N/A | 1 blood test taken during pregnancy | <p>Prenatal women can be certified without blood work if:</p> <ul style="list-style-type: none"> • at least one qualifying nutritional risk is present at certification and • blood test is obtained within 90 days of certification |
| Postpartum women | N/A | 1 blood test taken 4-6 weeks after end of pregnancy | None |
| Breastfeeding women | N/A | For women 6-12 months postpartum, no blood test is required if 1 test was taken after end of pregnancy | For women 6-12 months postpartum, no blood test is required if 1 test was taken after end of pregnancy |
| Infants <9 months | Not Required | Not Required | Not Required |
| Infants 9 months or older | Blood work required once between 9-12 months | Blood work required for infants certifying between 9-12 months | Blood work taken between 12-13 months can be used when no other blood work is available for infant category |
| Children 12-24 months | Blood work required once between 12-24 months (6 months after infant test)* | Blood work required at initial certification | |
| Children 24-60 months | N/A | All children are required to have blood work on an annual basis unless previous blood work result demonstrated nutritional risk eligibility for low Hgb. In this case, blood work is needed every 6 months. | |

*Blood work taken at or before the first birthday does not satisfy the requirement for both the infant blood work and the children's 12-24 month blood work. Separate blood work is required for each age range.

Appendix A - Blood Work Requirements, Options and Referrals

Pregnant Women

Blood work must be collected during the pregnancy.

Blood work is usually collected by WIC staff at the certification visit.

Results from an outside source (i.e. doctor's office) are also acceptable if it was collected during the pregnancy. If the results are not available at the Certification appointment, a note must be placed in the chart outlining the method and date by which the results will be reported. In the interim, the participant is placed on monthly pick-up, pending provision of blood work, for up to 60 days.

Women who are certified presumptively (with Risk 503) need to have blood work done within 90 days of certification.

They will be screened for all risks in 60 days, including anemia screening, if no other risk is found.

Postpartum & Breastfeeding Women

Blood work must be collected during the postpartum period:
Preferably within four to six weeks (30 - 45 days) after the termination of the pregnancy. Blood work is not valid if drawn before four weeks (30 days) postpartum.

The second blood test for breastfeeding women should be approximately six months postpartum. This second test is optional for women who had normal results from previous certification.

Blood work is usually collected by WIC staff at each certification visit. Results from an outside source (i.e., doctor's office) are acceptable if collected after four weeks postpartum and collected within 90 days of the certification date. This may be done only if another nutritional risk is present at the Certification appointment. The actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being recorded.

Appendix A - Blood Work Requirements, Options and Referrals

Infants

Blood tests are not required for infants under nine months of age. Blood work should be collected:

- Once between 9–12 months of age, and/or
- At the time of certification which begins after the infant has reached nine months of age.
- By WIC staff. Results from an outside source (i.e. doctor's office) are acceptable if drawn after nine months of age for a full-term infant or after six months of age for a premature infant. A blood test before nine months of age may also be appropriate for low birth weight infants who are not fed iron-fortified formula.
- If the blood is drawn at 12 months of age, the cutoffs used should be reflective of a one-year-old child status.

Children

Blood work must be done on all children at least once every 12 months after the child is 18 months old. The exception is if the blood work data was within normal limits (WNL) at or within their last certification, in which case, there may be a period of 14 months between blood tests. Children are at highest risk for anemia between 9 and 18 months of age.

- **Example:** Blood work taken at 10 months of age may be used to certify a 12 month old child. A blood test is required at the 15-18 month certification for all children.
- **Example:** A child's results were within normal limits (WNL) during the certification periods beginning at 12 months and 18 months. The test is optional at the 24-month certification.

Children 2-5 years old with low hemoglobin must have a blood test at six-month intervals. Blood work is usually collected by WIC staff at the Certification visit. Results from an outside source (i.e. doctor's office) are acceptable if drawn within 90 days of the certification date. The actual date that the blood test was performed must be entered into AIM. Do not use the date that it is being recorded. If no risk can be found at a certification, a blood test should be performed before ruling that the child is ineligible, even if the child's last result was normal.

- **Exception:** If the authorized representative waives the blood test after having the consequences explained to them, the child is then ruled ineligible.
-

Appendix A - Blood Work Requirements, Options, and Referrals

Children Continued

If the local agency has closed priorities, a blood test is recommended before placing a child on the waiting list.

Certification of a child who is new to the program will include a blood test, regardless of the age of the child.

Exception: The certification of a child who is an out-of-state transfer does not require a blood test. If a hemoglobin value from the child's most recent certification that is within normal limits is available on the Verification of Certification (VOC), that value may be entered.

Recommended Procedures

For hemoglobin results below the "Anemia" cutoff value:

The Community Nutrition Worker (CNW) will educate the participant or caregiver that WIC screens for (not diagnoses) anemia and counsels the participant on appropriate strategies to increase their iron levels.

For hemoglobin results outside the "Nutritionist" range:

If a client's hemoglobin value is outside the "Nutritionist" range for the first time, perform the procedure again. If possible, have a different person run the test on a different puncture site, such as an alternate finger or the infant's other heel. Record the higher of the two values in the AIM system.

Educate the participant or caregiver that WIC screens for (not diagnoses) anemia and since their value is outside of WIC's normal range, they will be referred to the nutritionist for further evaluation.

If the hemoglobin value remains outside of the "Nutritionist" range at their subsequent Certification, the CNW will automatically refer them to their healthcare provider. This is documented in the Referral section of the Care Plan screen in the AIM system.

Note: Poor technique may result in an abnormally low value.

Very low hemoglobin values:

A very low hemoglobin level is a serious medical concern and is life-threatening. Local Agencies must establish a referral plan and train staff to ensure that all participants with confirmed very low hemoglobin values are referred for an immediate medical evaluation, either with their primary care provider or, if unavailable, at an emergency medical center. Local Agencies will work with county/agency Health Program Officers to determine clinic referral procedures. All referrals must be documented in AIM.

Source: Phoenix Children's Hospital Laboratory Procedures

**Appendix A - Blood Work Requirements, Options, and Referrals
Table of Very Low Hemoglobin Values**

| | Hemoglobin Reading (<g/dL) |
|---|----------------------------|
| Altitude | |
| 0-2,999 (sea level) | 6.5 |
| 3000-3999 | 6.7 |
| 4000-4999 | 6.8 |
| 5000-5999 | 7.0 |
| 6000-6999 | 7.2 |
| 7000-7999 | 7.5 |
| 8000-8999 | 7.8 |
| 9000-9999 | 7.8 |
| 10,000 – 11,000 | 7.9 |
| Cigarette Smoking – add to cut off value | |
| 0.5 - < 1.0 pack per day | +0.3 |
| 1.0 - <2.0 packs per day | +0.5 |
| ≥2.0 packs per day | +0.7 |
| All smokers | +0.3 |

Appendix A - Blood Work Requirements, Options, and Referrals

| | |
|--------------------------|--|
| Use of 99.X codes | The 99.X codes are only to be used as placeholders in the 'Hgb' field in the Medical screen of the AIM system. They are not to be used in the height or weight fields. |
| 99.5 | <ul style="list-style-type: none">• The code 99.5 is to be used when blood work is pending. This indicates that the applicant is bringing the data from an outside source (i.e.: doctor's office). The applicant has ninety (90) days from the date of certification to bring in the data.• When 99.5 is entered, only one (1) month of Food Instruments are to be issued at a time. This can occur up to three (3) times. A note must be entered into the Notes box in the Medical screen in AIM. If the applicant does not bring in the data within ninety (90) days, they are to be terminated from the WIC Program.• When certifying postpartum women that are less than 4-6 weeks postpartum, a code of 99.5 should be used and one (1) month of Food Instruments should be issued. By their second postpartum WIC appointment, they will be able to have the blood work performed.• All applicants (except pregnant women) who have a 99.5 code for blood work must have another qualifying risk at the time of certification in order to be eligible for WIC Program benefits. Pregnant women can be certified as presumptively eligible for sixty (60) days, without a documented nutritional risk factor while their blood work is pending; blood work must be performed and a nutritional risk must be documented within sixty (60) days of certification. |
| 99.6 | The code 99.6 is used when hemophilia (a bleeding disorder found mostly in males) or a religious reason (i.e.: Christian Scientist) are present that prevent blood from being collected. This must be documented in the Notes box in the Medical screen in AIM. |
| 99.7 | The code 99.7 is to be used when blood work is not required at that certification (see table earlier in this Appendix). If a 99.7 code is used for a C2, C3, or C4 client, then there must be a normal hemoglobin result for the client, collected and recorded within less than one year. If a 99.7 code is used for a EN or PN, there must be a normal hemoglobin result for the client, collected and recorded when the women was four (4) or more weeks postpartum. If a 99.7 code is used for a C1, PG1 or PG2 client, there must be a normal hemoglobin result for the client, collected and recorded within less than five (5) months. For pregnant women, the normal hemoglobin result on record must have been collected during the current pregnancy. |
| 99.8 | The code 99.8 is used in situations where drawing blood will create a safety hazard to the client or the WIC staff member. This is not used in the case of HIV/AIDS, since staff should always use Universal Precautions (UP; see page 2) to protect themselves. The reason this code was used must be documented in the Notes box in the Medical screen in AIM. |

Appendix B – CDC Cutoffs for Anemia

Cutoff values for Hemoglobin Levels at 0-2,999 feet

| Smoking Status | action | Pregnant | | | Breastfeeding/Post-Partum | | Infant and Child | |
|-----------------------------------|--------------|-------------------------------|--------------------------------------|-----------------------------|--------------------------------------|-------------|-----------------------------|-----------------------|
| | | 1st Trimester 0 – 13 weeks | 2nd Trimester 14 – 26 weeks | 3rd Trimester 27 + weeks | 12 years to 14 years 11 months | 15 years + | Infant 6 to 23 months | Child 2 to 5 years |
| Non-Smoker | Anemia | 10.9 | 10.4 | 10.9 | 11.7 | 11.9 | 10.9 | 11.0 |
| | Nutritionist | 8.5 16.3 | 8.1 15.9 | 8.5 16.3 | 9.2 17.0 | 8.8 16.6 | 7.9 15.7 | 8.2 16.0 |
| up to 1 pack (1-19 cigarettes) | Anemia | 11.2 | 10.7 | 11.2 | 12.0 | 12.2 | | |
| | Nutritionist | 8.8 16.6 | 8.3 16.1 | 8.8 16.6 | 9.5 17.3 | 9.4 17.2 | | |
| 1-2 packs (20-39 cigarettes) | Anemia | 11.4 | 10.9 | 11.4 | 12.2 | 12.4 | | |
| | Nutritionist | 9.5 17.3 | 7.9 15.7 | 9.5 17.3 | 9.7 17.5 | 9.9 17.7 | | |
| 2+ packs (40+ cigarettes) | Anemia | 11.6 | 11.1 | 11.6 | 12.4 | 12.6 | | |
| | Nutritionist | 10.2 18.0 | 7.5 15.3 | 10.2 18.0 | 9.9 17.7 | 10.4 18.2 | | |

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 3,000-3,999 feet

| Smoking Status | action | Pregnant | | | Breastfeeding/Post-Partum | | Infant and Child | |
|-----------------------------------|--------------|-------------------------------|--------------------------------|-----------------------------|--------------------------------------|-------------|-----------------------------|-----------------------|
| | | 1st Trimester 0 – 13 weeks | 2nd Trimester 14 – 26 weeks | 3rd Trimester 27 + weeks | 12 years to 14 years 11 months | 15 years + | Infant 6 to 23 months | Child 2 to 5 years |
| Non-Smoker | Anemia | 11.1 | 10.6 | 11.1 | 11.9 | 12.1 | 11.1 | 11.2 |
| | Nutritionist | 9.0 16.8 | 8.6 16.4 | 9.0 16.8 | 9.4 17.2 | 9.3 17.1 | 8.3 16.1 | 8.7 16.5 |
| up to 1 pack (1-19 cigarettes) | Anemia | 11.4 | 10.9 | 11.4 | 12.2 | 12.4 | | |
| | Nutritionist | 9.3 17.1 | 8.8 16.6 | 9.3 17.1 | 9.7 17.5 | 9.8 17.6 | | |
| 1-2 packs (20-39 cigarettes) | Anemia | 11.6 | 11.1 | 11.6 | 12.4 | 12.6 | | |
| | Nutritionist | 10.0 17.8 | 8.4 16.2 | 10.0 17.8 | 9.9 17.7 | 10.3 18.1 | | |
| 2+ packs (40+ cigarettes) | Anemia | 11.8 | 11.3 | 11.8 | 12.6 | 12.8 | | |
| | Nutritionist | 10.7 18.5 | 8.0 15.8 | 10.7 18.5 | 10.1 17.9 | 10.8 18.6 | | |

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 4,000-4,999 feet

| Smoking Status | action | Pregnant | | | Breastfeeding/Post-Partum | | Infant and Child | |
|-----------------------------------|--------------|-------------------------------|--------------------------------|-----------------------------|--------------------------------------|-------------|-----------------------------|-----------------------|
| | | 1st Trimester 0 – 13 weeks | 2nd Trimester 14 – 26 weeks | 3rd Trimester 27 + weeks | 12 years to 14 years 11 months | 15 years + | Infant 6 to 23 months | Child 2 to 5 years |
| Non-Smoker | Anemia | 11.2 | 10.7 | 11.2 | 12.0 | 12.2 | 11.2 | 11.3 |
| | Nutritionist | 9.1 16.9 | 8.8 16.6 | 9.1 16.9 | 9.5 17.3 | 9.4 17.2 | 8.4 16.2 | 8.8 16.6 |
| up to 1 pack (1-19 cigarettes) | Anemia | 11.5 | 11.0 | 11.5 | 12.3 | 12.5 | | |
| | Nutritionist | 9.4 17.2 | 9.0 16.8 | 9.4 17.2 | 9.8 17.6 | 9.9 17.7 | | |
| 1-2 packs (20-39 cigarettes) | Anemia | 11.7 | 11.2 | 11.7 | 12.5 | 12.7 | | |
| | Nutritionist | 10.2 18.0 | 8.6 16.4 | 10.2 18.0 | 10.0 17.8 | 10.4 18.2 | | |
| 2+ packs (40+ cigarettes) | Anemia | 11.9 | 11.4 | 11.9 | 12.7 | 12.9 | | |
| | Nutritionist | 10.9 18.7 | 8.2 16.0 | 10.9 18.7 | 10.2 18.0 | 10.9 18.7 | | |

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 5,000-5,999 feet

| Smoking Status | action | Pregnant | | | Breastfeeding/Post-Partum | | Infant and Child | |
|-----------------------------------|--------------|-------------------------------|--------------------------------|-----------------------------|-----------------------------------|-------------|--------------------------|-----------------------|
| | | 1st Trimester 0 – 13 weeks | 2nd Trimester 14 – 26 weeks | 3rd Trimester 27 + weeks | 12 years to 14 years 11 months | 15 years + | Infant 6 to 23 months | Child 2 to 5 years |
| Non-Smoker | Anemia | 11.4 | 10.9 | 11.4 | 12.2 | 12.4 | 11.4 | 11.5 |
| | Nutritionist | 9.3 17.1 | 8.9 16.7 | 9.3 17.1 | 9.7 17.5 | 9.5 17.3 | 8.5 16.3 | 8.9 16.7 |
| up to 1 pack (1-19 cigarettes) | Anemia | 11.7 | 11.2 | 11.7 | 12.5 | 12.7 | | |
| | Nutritionist | 9.6 17.4 | 9.2 17.0 | 9.6 17.4 | 10.0 17.8 | 10.1 17.9 | | |
| 1-2 packs (20-39 cigarettes) | Anemia | 11.9 | 11.4 | 11.9 | 12.7 | 12.9 | | |
| | Nutritionist | 10.3 18.1 | 8.8 16.6 | 10.3 18.1 | 10.2 18.0 | 10.6 18.4 | | |
| 2+ packs (40+ cigarettes) | Anemia | 12.1 | 11.6 | 12.1 | 12.9 | 13.1 | | |
| | Nutritionist | 11.0 0.0 | 8.4 16.2 | 11.0 18.8 | 10.4 18.2 | 11.1 18.9 | | |

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 6,000-6,999 feet

| Smoking Status | action | Pregnant | | | Breastfeeding/Post-Partum | | Infant and Child | |
|-----------------------------------|--------------|-------------------------------|--------------------------------|-----------------------------|--------------------------------------|-------------|-----------------------------|-----------------------|
| | | 1st Trimester 0 – 13 weeks | 2nd Trimester 14 – 26 weeks | 3rd Trimester 27 + weeks | 12 years to 14 years 11 months | 15 years + | Infant 6 to 23 months | Child 2 to 5 years |
| Non-Smoker | Anemia | 11.6 | 11.1 | 11.6 | 12.4 | 12.6 | 11.6 | 11.7 |
| | Nutritionist | 9.4 17.2 | 9.1 16.9 | 9.4 17.2 | 9.9 17.7 | 9.7 17.5 | 8.7 16.5 | 9.1 16.9 |
| up to 1 pack (1-19 cigarettes) | Anemia | 11.9 | 11.4 | 11.9 | 12.7 | 12.9 | | |
| | Nutritionist | 9.7 17.5 | 9.3 17.1 | 9.7 17.5 | 10.2 18.0 | 10.2 18.0 | | |
| 1-2 packs (20-39 cigarettes) | Anemia | 12.1 | 11.6 | 12.1 | 12.9 | 13.1 | | |
| | Nutritionist | 10.5 18.3 | 8.9 16.7 | 10.5 18.3 | 10.4 18.2 | 10.7 18.5 | | |
| 2+ packs (40+ cigarettes) | Anemia | 12.3 | 11.8 | 12.3 | 13.1 | 13.3 | | |
| | Nutritionist | 11.2 19.0 | 8.5 16.3 | 11.2 19.0 | 10.6 18.4 | 11.2 19.0 | | |

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC
Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Cutoff values for Hemoglobin Levels at 7,000-7,999 feet

| Smoking Status | action | Pregnant | | | Breastfeeding/Post-Partum | | Infant and Child | |
|-----------------------------------|--------------|-------------------------------|--------------------------------|-----------------------------|--------------------------------------|-------------|-----------------------------|-----------------------|
| | | 1st Trimester 0 – 13 weeks | 2nd Trimester 14 – 26 weeks | 3rd Trimester 27 + weeks | 12 years to 14 years 11 months | 15 years + | Infant 6 to 23 months | Child 2 to 5 years |
| Non-Smoker | Anemia | 11.9 | 11.4 | 11.9 | 12.7 | 12.9 | 11.9 | 12.0 |
| | Nutritionist | 9.6 17.4 | 9.3 17.1 | 9.6 17.4 | 10.2 18.0 | 9.8 17.6 | 8.8 16.6 | 9.2 17.0 |
| up to 1 pack (1-19 cigarettes) | Anemia | 12.2 | 11.7 | 12.2 | 13.0 | 13.2 | | |
| | Nutritionist | 9.9 17.7 | 9.5 17.3 | 9.9 17.7 | 10.5 18.3 | 10.4 18.2 | | |
| 1-2 packs (20-39 cigarettes) | Anemia | 12.4 | 11.9 | 12.4 | 13.2 | 13.4 | | |
| | Nutritionist | 10.6 18.4 | 9.1 16.9 | 10.6 18.4 | 10.7 18.5 | 10.8 18.6 | | |
| 2+ packs (40+ cigarettes) | Anemia | 12.6 | 12.1 | 12.6 | 13.4 | 13.6 | | |
| | Nutritionist | 11.3 19.1 | 8.7 16.5 | 11.3 19.1 | 10.9 18.7 | 11.3 19.1 | | |

Hemoglobin values at or below the "Anemia" cutoff are reported as anemic in WIC

Hemoglobin values outside the "Nutritionist" range are referred to a Nutritionist

Appendix C - Staff Competency Check List

Staff Competency Check List

Staff Name: _____

Completed = ✓

Not met = ✗

Supervisor: _____

Grade = # of ✓ ÷ 16 x 100 = ___ %

| PROCEDURE | #1 | #2 | #3 | COMMENTS |
|---|----|----|----|----------|
| 1. Identify client | | | | |
| 2. Cleanse hands (can glove hands now if desired) | | | | |
| 3. Assemble supplies & glove hands, if not done already | | | | |
| 4. Position client & choose site | | | | |
| 5. Warm site (if necessary) | | | | |
| 6. Cleanse puncture site and dry | | | | |
| 7. Hold site firmly & pull skin taut | | | | |
| 8. Puncture skin (correct site and depth) | | | | |
| 9. Wipe off first 2-3 drops (no milking) | | | | |
| 10. Cuvette tip pointed down, filled in one step (no bubbles or layers) | | | | |
| 11. Apply pressure & bandage (if appropriate) | | | | |
| 12. Wipe excess blood from outside of cuvette | | | | |
| 13. Correctly dispose of used supplies | | | | |
| 14. Remove & dispose of gloves, cleanse hands | | | | |
| 15. Record results | | | | |
| 16. Clean surface | | | | |

Scores = ___ ___ ___ → Avg. Score ___

Staff Signature _____ Date: _____

Supervisor Signature _____ Date: _____

Appendix D – Contact List

HemoCue Technical Support

You should only contact HemoCue directly if you are instructed to do so by ADHS staff.

HemoCue Technical Support: (800) 426-7256

Arizona Department of Health Services HemoCue Equipment Support

If you are experiencing issues with HemoCue equipment, you must follow the procedures in Appendix F of this manual.

If you are unable to access the HemoCue Troubleshooting Assistance Request Form on the azwic.gov website (as detailed in Appendix F), you may call (602) 542-1886 and ask for:

1st Contact:

WIC Community Services Team Administrative Assistant



2nd Contact:

WIC Community Services Team Program Consultant



3rd Contact:

WIC Community Services Team Manager

Appendix E – HemoCue[®] Hb 201⁺ System Maintenance Log

Appendix F – Trouble Shooting Guide

US **Trouble Shooting Guide**

If you are unable to resolve the problem by following this Trouble Shooting Guide, please contact HemoCue Inc. The analyzer has no serviceable parts.

| Symptom | Explanation | Action |
|-----------------------------------|--|---|
| The analyzer shows an error code. | May be a temporary fault. | Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, see specific error code below. |
| E00 | No stable endpoint is found within the time range. 1. The cuvette is faulty. 2. The circuit board is out of order. | 1a. Check the expiration date for the microcuvettes. 1b. Take a new microcuvette and repeat the measurement. 2. The analyzer needs service. Contact HemoCue, Inc. |
| E01–E05 | 1. Dirty optronic unit or faulty electronic or optronic unit. | 1a. Turn off the analyzer and clean the optronic unit as described in the maintenance section. 1b. The analyzer needs service. Contact HemoCue, Inc. |
| E06 | 1. Unstable blank value The analyzer might be cold. | 1. Turn off the analyzer and allow it to reach room temperature. If the problem continues, the analyzer needs service. Contact HemoCue, Inc. |
| E07 | 1. The battery power is too low. | 1a. The batteries need to be replaced. Turn off the analyzer and replace the batteries, 4 type AA. 1b. Use the power adapter. |
| E08 | The absorbance is too high. 1. An item is blocking the light in the cuvette holder. | 1a. Check that the analyzer and microcuvettes are being used according to the HemoCue Hb 201 ⁺ operating manual and instructions for use. 1b. The analyzer needs service. Contact HemoCue, Inc. |
| E09–E30 | 1. Dirty optronic unit or faulty electronic or optronic unit. | 1a. Turn off the analyzer and clean the optronic unit as described in the maintenance section. 1b. The analyzer needs service. Contact HemoCue, Inc. |

| Symptom | Explanation | Action |
|---|--|--|
| HHH | <ol style="list-style-type: none"> 1. Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L). | |
| No characters on the display | <ol style="list-style-type: none"> 1. The analyzer is not receiving power. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order. | <ol style="list-style-type: none"> 1a. Check that the power adapter is connected to the AC power supply. 1b. Check that the power adapter is securely connected to the analyzer. 1c. Check that the cable is not damaged. <ol style="list-style-type: none"> 2. Turn off the analyzer and replace the batteries, 4 type AA. 3. The analyzer needs service. Contact HemoCue, Inc. |
| The display gives erroneous characters. | <ol style="list-style-type: none"> 1. The display is out of order. 2. The microprocessor is out of order. | <ol style="list-style-type: none"> 1. The analyzer needs service. Contact HemoCue, Inc. 2. The analyzer needs service. Contact HemoCue, Inc. |
| The display shows "▣". | <ol style="list-style-type: none"> 1. The batteries need to be replaced. 2. If on mains power, the mains adapter or the circuit board is out of order. | <ol style="list-style-type: none"> 1. Turn off the analyzer and replace the batteries, 4 type AA. 2a. Check that the power adapter is properly connected and working. 2b. The analyzer needs service. Contact HemoCue, Inc. |
| The display does not switch from "⊘" and "Hb" to three flashing dashes and "⊘" (ready for measuring). | <ol style="list-style-type: none"> 1. The magnet in the cuvette holder may be missing. 2. The magnetic sensor is out of order. | <ol style="list-style-type: none"> 1. The analyzer needs service. Contact HemoCue, Inc. 2. The analyzer needs service. Contact HemoCue, Inc. |
| Measurements on patient samples are higher or lower than anticipated. | <ol style="list-style-type: none"> 1. Improper sampling technique. 2. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 3. The optical eye of the microcuvette is contaminated. 4. Air bubbles in the microcuvette. 5. The optronic unit is dirty. 6. The calibration of the analyzer has changed. | <ol style="list-style-type: none"> 1. See pages 8–17 in this manual. 2. Check the expiration date and the storage conditions of the microcuvettes. Check the entire system with a commercial control. 3. Remeasure the sample with a new microcuvette. 4. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 5. Clean the optronic unit as described in the maintenance section. 6. The analyzer needs service. Contact HemoCue, Inc. |

Appendix G – CLIA Application for Certification

III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

- | | | |
|---|---|---|
| <input type="checkbox"/> 01 Ambulance | <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 22 Practitioner Other (Specify) |
| <input type="checkbox"/> 02 Ambulatory Surgery Center | <input type="checkbox"/> 11 Health Main. Organization | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility | <input type="checkbox"/> 12 Home Health Agency | <input type="checkbox"/> 24 Public Health Laboratories |
| <input type="checkbox"/> 04 Assisted Living Facility | <input type="checkbox"/> 13 Hospice | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 05 Blood Bank | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 26 School/Student Health Service |
| <input type="checkbox"/> 06 Community Clinic | <input type="checkbox"/> 15 Independent | <input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 28 Tissue Bank/Repositories |
| <input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 29 Other (Specify) |
| <input type="checkbox"/> 09 Federally Qualified Health Center | <input type="checkbox"/> 18 Intermediate Care Facility for Mentally Retarded | |
| | <input type="checkbox"/> 19 Mobile Laboratory | |
| | <input type="checkbox"/> 20 Pharmacy | |
| | <input type="checkbox"/> 21 Physician Office | |

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

| | SUNDAY | MONDAY | TUESDAY | WEDNESDAY | THURSDAY | FRIDAY | SATURDAY |
|-------|--------|--------|---------|-----------|----------|--------|----------|
| FROM: | | | | | | | |
| TO: | | | | | | | |

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?

- No. If no, go to section VI. Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?

- Yes No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

- Yes No

If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

- Yes No

If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here and attach the additional information using the same format.

| NAME AND ADDRESS / LOCATION | | TESTS PERFORMED / SPECIALTY / SUBSPECIALTY |
|---|----------------------------|--|
| Name of Laboratory or Hospital Department | | |
| Address/Location (Number, Street, Location if applicable) | | |
| City, State, ZIP Code | Telephone Number () | |
| Name of Laboratory or Hospital Department | | |
| Address/Location (Number, Street, Location if applicable) | | |
| City, State, ZIP Code | Telephone Number () | |

IX. TYPE OF CONTROL

| VOLUNTARY NONPROFIT | FOR PROFIT | GOVERNMENT | |
|------------------------------------|-------------------|-------------------|---------------------------|
| 01 Religious Affiliation | 04 Proprietary | 05 City | 08 Federal |
| 02 Private | | 06 County | 09 Other Government |
| 03 Other _____ <i>(Specify)</i> | | 07 State | _____ <i>(Specify)</i> |

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

| CLIA NUMBER | NAME OF LABORATORY |
|-------------|--------------------|
| | |
| | |
| | |
| | |
| | |

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

| | |
|--|------|
| SIGNATURE OF OWNER/DIRECTOR OF LABORATORY <i>(Sign in Ink)</i> | DATE |
|--|------|

