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Chapter 1. Introduction

Purpose

The purpose of the Arizona Department of Health Services (ADHS), Bureau of Nutrition & Physical Activity (BNPA) 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 manual is designed to be user-friendly.

HemoCue Analyzers

Effective January 1, 2010, the Arizona WIC Program transitioned to the HemoCue® 201+ analyzers. For children under 2 years old who require screening for anemia HemoCue 201+ analyzers are the primary measurement method for hemoglobin status. 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.

Note: Since 2018 HemoCue offers a 301+ analyzer with improved self-calibration frequency and faster results. Expiration dates marked on unopened vial containers for 301+ cuvettes do not change after opening. Both 201+ and 301+ analyzers are approved for use by the Arizona WIC program.

Masimo Pronto Pulse CO-Oximeters

Beginning in September 2012, Arizona WIC introduced the Masimo Pronto Pulse CO-Oximeter as the primary measurement method for hemoglobin status in adults and children 2 years and older. It replaces the HemoCue analyzer for all WIC participants at least 2 years old except for circumstances when a reading cannot be obtained using the Pronto. The Pronto has been cleared for use in the clinical setting by FDA because it is both accurate and reliable compared with the reference standard measurement for venous hemoglobin. (Postgraduate Medicine, a peer reviewed journal for physicians, compared results using both the Masimo Pronto and Hemocue 201 hemoglobin analyzers. The author concluded that the Pronto results were similar to that of the Hemocue analyzer.)

For situations in which a measurement cannot be obtained using the Masimo Pronto, or for children under two years of age who require hemoglobin measurement, the HemoCue Analyzer will continue to be used.
Chapter 2. Safety and Universal Precautions

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 Immuno-deficiency 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.

Exposure Control Plan and 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.
Safety Continued

Personal Work Practices Continued

The single most important means of preventing the spread of infection is hand-washing. Wash your hands:

- At the beginning and end of your shift
- Before a skin puncture and after removing your gloves
- Before using the Masimo Pronto (see Chapter 11. Test Preparation and Performing a Reading)
- After physical contact with participants. For example, after weighing an infant in diaper only, or positioning a child's head for height measurement.
- 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."
- **Note:** 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.

**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.
- 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 Heel Punctures**: Single-Use Capillary Blood Sampling Device, **1.8mm needle**. (for infants 9-18 months and children with very small fingers)

- **For children 12-18 months of age use a 1.8mm lancet** to perform a heel stick or a finger puncture:
  - Staff may use their discretion to perform a heel stick with 1.8 mm lancet OR a finger puncture with a 1.8 mm lancet.

- **Recommended Lancet for Finger Punctures**: Single-Use Capillary Blood Sampling Device, **2.25mm needle**. (for children >18 months and adults).

- Always clean the work site at the beginning and end of each workday. Also clean the work site after any contact with blood or other potentially infectious materials.

- Use a prepared bleach solution (instructions below) or an EPA-registered disinfectant that is effective as a tuberculocidal and kills Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV).

  A list of EPA-registered disinfectants can be found at the following address: [https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants](https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants) Be sure to read descriptions carefully and choose a disinfectant that is effective against TB, HIV, and 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:
     - If using bleach solution, 10 minutes
     - If using premixed solution, longest kill time listed on label
  4) Dispose of the infectious waste in accordance with federal, state, or local regulations (see clinic exposure control plan)

- 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.
### Safety Continued

**Preparation and Storage of Disinfectant Solution**

- Prepare a fresh bleach (5.25% sodium hypochlorite) solution **daily**.
- 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.

**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 contain 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.
## Chapter 3. Information About Blood Testing

<table>
<thead>
<tr>
<th>Type of Blood Tests</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin Testing</td>
<td>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.</td>
</tr>
<tr>
<td>Milking</td>
<td>To press out, drain off, remove, or draw out blood as if by milking. Squeezing/milking dilutes the blood and gives a false low reading. Low readings obtained from squeezing/milking may falsely indicate the possibility of anemia.</td>
</tr>
<tr>
<td>Anemia</td>
<td>A low hemoglobin test result indicates the possibility of anemia. Anemia is a condition in which there are low levels of hemoglobin 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)</td>
</tr>
<tr>
<td>Anemia Cutoffs</td>
<td>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.</td>
</tr>
<tr>
<td>Correct Values</td>
<td>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.</td>
</tr>
</tbody>
</table>
Information about Blood Testing Continued

**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 once every three years by ADHS Bureau of Nutrition & Physical Activity to ensure competency.

**Laboratory Certification**

The Local Agency Director or designee is responsible for obtaining and maintaining a Certificate of Waiver in accordance with Clinical Laboratory Improvement Amendment (CLIA) regulations. The Clinical Laboratory Program, regulates all laboratory testing (except research) performed on humans, under the Clinical Laboratory Improvement Amendment (CLIA). CLIA is the Clinical Laboratory Improvement Amendments and is regulated by the federal government through the state agency, the regional office and the central office.

A laboratory may apply for a CLIA certificate through the Office of Laboratory Licensure and Certification (OLLC), CLIA Program. Call (602) 364-0738, or write to 250 N. 17th Avenue, Phoenix, AZ 85007-3231.

Payments are sent to:

CLIA Laboratory Program  
P.O. Box 530882  
Atlanta, GA 30353-0882

Checks should be made out to CLIA Laboratory Program and should include the CLIA number on the check to ensure that the payment is applied to the correct account. Do not send payments to the state. Payments may also be made online at Pay.gov.

Contact OLLC at (602) 364-0738 or Denise Barbeau for a change of ownership, director, or address, or to request an application.

Note: Arizona does not currently have state licensure for clinical laboratories and does not license clinical laboratory testing personnel and phlebotomists.

For additional information, please visit cms.gov. Additional questions may be directed to your WIC Nutrition Consultant.
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
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.

Note: The HemoCue 301+ analyzer measures with similar accuracy to the 201+ analyzer, completing measurements within 3 seconds.

Storage of Cuvettes
- Store cuvettes at room temperature. Do not expose to any direct heat source.
- Label the vial with the date on which the contents of the vial expire (vial expires 90 days after opening). Note: Labeling the date on which the vial is opened is no longer required. 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.

Note: Cuvettes for the 301+ analyzer are not affected by the date the vial is opened. 301+ Cuvettes do not have reagent in the tip, so they are unaffected by humidity and moisture.
### Chapter 4. Daily Steps for Performing Hemoglobin Tests with HemoCue

#### Identify Client
Prior to any lab testing, explain the Rights & Obligations for program participation to the participant or authorized representative. Verify understanding and obtain consent before asking the responsible individual to sign the signature pad. (The Rights & Obligations form may be selected by using the Signatures button located at the bottom of the Medical Screen in HANDS.)

Note: If the signature pad is unavailable or not working you may print a paper copy of the Rights & Obligations. For paper Rights & Obligations forms 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, especially when using an invasive hemoglobin test such as the HemoCue 201.

**Example (using the HemoCue 201):**
"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 participants. If a participant 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 sanitizer 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
BEFORE assembling supplies and putting on gloves: Wash hands with soap and water.
- HemoCue® Analyzer
- Gloves
- Alcohol prep pads
- Sterile lancets
- Lint-free tissues/KimWipes® or Gauze pads
- Closed vial of cuvettes (remove 1 at a time & recap container)
- Bandages (not for children under age 2)
- Sharps container
- Biohazard bag
- 10% bleach solution or EPA-registered disinfectant
- Soap and water, alcohol-based hand sanitizer or hand wipes

AFTER assembling supplies, put on gloves if you haven’t already done so.
### Daily Steps for Performing Hemoglobin Tests Continued

<table>
<thead>
<tr>
<th>Position Client</th>
<th>For infants and children with very small fingers up to 18 months of age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Have a seated adult hold the infant/child over adult’s shoulder, or have baby lay face-down across adult’s lap for heel stick.</td>
</tr>
</tbody>
</table>

**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.

1. For children 12-18 months it is at the staff’s discretion to continue with a heel stick or to use a smaller 1.8mm lancet on their finger.
2. Children over 18 months of age should **NOT** receive a heel stick.
3. **For everyone else,** seat client and extend arm with palm up.

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

<table>
<thead>
<tr>
<th>Choose Site</th>
<th>Heel - For infants and children with very small fingers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

*Do not "milk" the heel to speed the process. Squeezing/milking dilutes the blood and gives a false low reading*

<table>
<thead>
<tr>
<th>Finger - For everyone else</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sea the participant or ask someone to help with a child.</td>
</tr>
</tbody>
</table>

- For example, 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.
- *Do not "milk" the finger to speed the process. Squeezing/milking dilutes the blood and gives a false low reading*

<table>
<thead>
<tr>
<th>Warm the Site (If Necessary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The site should not be cold, blue, swollen or calloused.</td>
</tr>
</tbody>
</table>

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.
Daily Steps for Performing Hemoglobin Tests Continued

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. Avoid milking the site.

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.
Daily Steps for Performing Hemoglobin Tests Continued

**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.

---

**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.

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 new cuvette.

---

**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 begin and the result will appear on the display within 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.
Daily Steps for Performing Hemoglobin Tests Continued

When to Run a Second Test

Occasionally, a second test must be run, such as when the displayed hemoglobin value is in the “Nutritionist” range (see P&P Chapter 2, Appendix P). 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 HANDS 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.

Very low hemoglobin values

A very low hemoglobin level is a serious medical concern and is life-threatening. Local Agencies shall 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 shall be documented in HANDS.

See Appendix B – Very Low Hemoglobin Values table of cutoff values
See P&P Chapter 2, Appendix P for more information about 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

Wastebasket: 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.

Biohazard bag: 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.

Sharps container: Throw away all lancets and used cuvettes in the sharps container.
Daily Steps for Performing Hemoglobin Tests Continued

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.

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

Blood Work Requirements, Options and Referrals

Hemoglobin participant category screening requirements
For information about hemoglobin screening policy, participant category screening requirements (including the quick reference table), and allowed exceptions for hemoglobin screening see P&P Chapter 2, Appendix P [http://azdhs.gov/prevention/azwic/agencies/index.php#manuals].

Cutoff levels for Anemia, Nutritionist range, and Very Low Hemoglobin values
For information about “Anemia” cutoff values, “Nutritionist” range cutoff values and “Very Low Hemoglobin” cutoff values see P&P Chapter 2, Appendix P. [http://azdhs.gov/prevention/azwic/agencies/index.php#manuals]

HANDS Pending Codes for Anthropometry and Bloodwork
For Information about HANDS Pending Codes for Anthropometry and Bloodwork see P&P Chapter 2, Appendix Q. [http://azdhs.gov/prevention/azwic/agencies/index.php#manuals]
Chapter 5. Administration & Maintenance of HemoCue® Equipment for the Local Agencies
(see Chapter 15 for Administration and Maintenance of the Masimo Pronto)

| Equipment | The state agency occasionally receives working HemoCue analyzers that are no longer needed. Please contact your Nutrition Services consultant to acquire additional Hb 201 analyzers. Local agencies are responsible for procuring all related supplies for hemoglobin screening. Cuvettes will be purchased by local agencies directly from HemoCue. Please place your order with:

Sharon Bynum  
sharon.l.bynum@hemocue.com  
972-249-5202  
Please specify the type of analyzer when ordering cuvettes (201+ replacement cuvettes or 301+ replacement cuvettes)

Part Number 111716 for HemoCue Microcuvettes
Order by the box. One box has 200 microcuvettes (4 vials of 50 each).
**For agencies that need smaller quantities: Part Number 111715 for individually wrapped HemoCue Microcuvettes in 100-pack

301+ Cuvettes: One box has 300 microcuvettes (4 vials of 75 each)

| HemoCue Inventory Control - Equipment Returns or Replacements (see Chapter 15 for Masimo Pronto) | 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 quantity of analyzers will also be available for order at the state agency. Please contact your WIC Nutrition Consultant to order analyzers. |
## Chapter 5. Administration & Maintenance of HemoCue® Equipment for the Local Agencies Continued

<table>
<thead>
<tr>
<th>Quality Control</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance of the Analyzer</td>
<td>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. <strong>Note:</strong> 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.</td>
</tr>
<tr>
<td>Chain of Support for Troubleshooting</td>
<td>The following chain of support should be followed when resolving challenges with the Analyzer ONLY AFTER THE ERROR HAS BEEN ADDRESSED WITHOUT RESOLUTION: 1&lt;sup&gt;st&lt;/sup&gt; Contact – Site Supervisor 2&lt;sup&gt;nd&lt;/sup&gt; Contact – Site Supervisor or Local Agency HemoCue Lead will call the state WIC Nutrition Consultant to report the problem. The state contact will walk the Local Agency through correcting the problem. 3&lt;sup&gt;rd&lt;/sup&gt; 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.</td>
</tr>
<tr>
<td>Problems with the HemoCue® Analyzer</td>
<td></td>
</tr>
<tr>
<td>System Maintenance Log</td>
<td>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.</td>
</tr>
</tbody>
</table>
## Chapter 6. Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accuracy</strong></td>
<td>The agreement of results with the true value for specimens measured.</td>
</tr>
<tr>
<td><strong>Anemia</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Biohazard Bag/Container</strong></td>
<td>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 &quot;Biohazard&quot;).</td>
</tr>
<tr>
<td><strong>Calibration</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>CLIA ('88)</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Cuvette</strong></td>
<td>A small transparent container in which solutions are placed for photometric analysis.</td>
</tr>
<tr>
<td><strong>EPA-registered Disinfectant</strong></td>
<td>A cleanser that is recognized by the Environmental Protection Agency as being effective against specific pathogens. For blood exposure OSHA requires the use of disinfectants effective against tuberculosis-causing bacteria as well as HIV &amp; HBV to decontaminate work surfaces.</td>
</tr>
<tr>
<td><strong>Hemoglobin</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Hemolysis</strong></td>
<td>The destruction of red blood cell membrane causing release of hemoglobin into surrounding serum or plasma.</td>
</tr>
<tr>
<td><strong>Iron Deficiency Anemia</strong></td>
<td>Anemia resulting from iron depletion as evidenced by laboratory testing methods such as serum ferritin or transferrin.</td>
</tr>
<tr>
<td><strong>Lancet</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
### Glossary Continued

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milking</td>
<td>To press out, drain off, remove, or draw out blood as if by milking.</td>
</tr>
<tr>
<td>Rocking</td>
<td>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).</td>
</tr>
<tr>
<td>Sharps</td>
<td>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.</td>
</tr>
<tr>
<td>Universal Precautions</td>
<td>A set of rules established by the CDC, and adopted by OSHA, to control infection from bodily fluids in the health care setting.</td>
</tr>
<tr>
<td>Standard Precautions</td>
<td>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.</td>
</tr>
<tr>
<td>Vial</td>
<td>A small container with a lid, used especially for storing liquids.</td>
</tr>
</tbody>
</table>
Chapter 7. Bibliography


Chapter 8. Using the Masimo Pronto

How It Works

The Masimo Pronto measures total hemoglobin concentration of the blood. The sensor attached to the machine emits multiple lightwaves through the capillary bed of the fingertip. Changes in the light absorption can be used to measure the functional arterial oxygen saturation of the blood, from which the hemoglobin concentration can be calculated. (In a similar way the HemoCue Analyzer emits wavelengths of light to calculate total hemoglobin by the degree of light absorption in the blood droplet collected in a cuvette.)

Safety

Conducting a hemoglobin spot check is noninvasive and requires no blood. The Masimo Pronto is safe to use outside of the lab area. There is no risk of transmitting bloodborne diseases to WIC staff or other WIC participants when conducting spot checks with the Pronto device. Hand-washing procedures and antibacterial agents (such as hand sanitizer and alcohol wipes) are required to prevent the transmission of contagious diseases. The use of gloves is not necessary for the safety of staff or participants.

Choosing a Location

The selected location for using the Pronto device should be a comfortable area, free of excessive noise or distractions.

Note: It is not recommended to conduct hemoglobin tests with the Pronto device in a common lab area where other measurements or finger pokes are made. The sights and sounds of other participants who may be stressed or upset by lab procedures will make it more difficult to keep participants relaxed and motionless when using the Pronto.

When To Use

The Pronto replaces the HemoCue analyzer for all WIC participants at least 2 years old including women, except for circumstances when a reading cannot be obtained using the Pronto. The Pronto has been cleared for use in the clinical setting by FDA. An independent study in a peer-reviewed scientific journal concluded that the bias and standard deviation for the Pronto results were similar to that of the HemoCue analyzer.
Chapter 9. Equipment Needed

- Equipment needed to conduct tests using the Masimo Pronto Pulse CO-Oximeter:
  - Masimo Pronto Pulse CO-Oximeter unit

- RC1 Patient Cable

  One foot patient cable that connects to rainbow DCI and rainbow DC-IP

- Rainbow DCI Digit Sensor (Adult sized, includes slender digit gauge)

- Rainbow DCIP Digit Sensor (Pediatric sized)
Sensor Options for Pronto Device

- Rainbow DCI and DCIP reusable sensors are indicated for Spot Check monitoring of SpO2 and SpHb with the Pronto Device
- These sensors can be utilized on both adult and pediatric patients depending on finger size

### Slender Digit Gauge

- Aids in selecting an appropriate digit for sensor application.
- Remove the gauge from the digit before sensor application

### Pronto Battery Compartment

- Battery Compartment located in back panel
- Holds 4 “AA” alkaline or rechargeable batteries
- Operates up to 8 hours
Chapter 10. Initializing the Pronto for Clinic Use

Setting up a new device:
- Open box, remove the device (enclosed in rubber casing) from box.
- Remove the device from rubber boot.
- On back of machine near the bottom is the housing for four AA batteries.
  Depress tab to allow battery cover to slide away. Insert batteries according to illustrated graphic guide inside battery case.
- Device will activate automatically. If machine goes to sleep, or if batteries already inserted, press green power button underneath up/down arrow buttons.

Pronto Display

- Parameter/Measurement Numeric Display
- Low SIQ Indicator
- Pulse Indicator
- Spot Check Progress Indicator
- Sensor Use Indicator
- SpHb Parameter Label
- Battery Level Indicator

Parameter/Measurement Display

- Parameter/Measurement Numeric Display - Displays parameter/measurement numeric values once a spot check test is complete.

Pulse Indicator

- Pulse Indicator - Flashes with patient’s pulse reading (BPM) during spot check
test period.

**Spot Check Progress Indicator**

- Spot Check Progress Indicator - Incrementally illuminates upward after a SpHb spot check has been initiated. This indicates progress towards completion of a SpHb spot check. A fully illuminated spot check progress indicator indicates a completed spot check.

**Parameter/ Measurement Label Display**

- Parameter/ Measurement Label Display - Displays parameter/measurement label once a spot check test is complete.

**Battery Level Indicator**

- Battery Level Indicator - Battery charge level is indicated by four LED indicators. All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge.

**Low SIQ Indicator**

- Low SIQ Indicator - SIQ is a signal identification and confidence indicator. When this indicator illuminates, re-checking the measurement is necessary.

**Sensor Use Indicator**

- Sensor Use Indicator - This illuminates to display the approximate number of uses remaining for the attached sensor. The bottom LED will turn red when the remaining uses for the connected sensor are low. The approximate number of
sensor uses remaining is displayed upon power up (if a sensor is attached) and when a sensor is connected.

**Pronto Controls**

- **Power On/Off Button**
  - Powers the instrument on or off. Press the button once to power on, press and hold the Button for 2 seconds to power off.

- **SpHb Button**
  - Press to initiate total hemoglobin (SpHb) spot check information on display or to display a Total Hemoglobin (SpHb) spot check test. If configured, oxygen saturation (SpO2), perfusion index (PI) and pulse rate (PR) are automatically displayed. When in the configuration menu, pressing this button will confirm a menu setting and navigate to the next menu option.
Up/Down

- **Up/Down** – Use the Up and Down arrow buttons to scroll between parameter or measurement spot check results. When in the configuration menu, use the Up and Down arrow buttons to scroll through menu setting options.

When initializing the device, the year, month, day, and time will need to be set.

1. Press Up and Down arrow buttons simultaneously for 5 seconds
   a) “Yr” (year) number, press arrow to change year number to last two digits of current year
   b) Press SpHb
   c) “nn” (with a number below) indicates month, use arrows to enter correct month
   d) Press SpHb
   e) After month repeat procedure for day, hour, minute
   f) Anytime the machine times out and returns to “00” and “Cbl” (no cable), it can be reactivated by pressing the up/down buttons
   g) Press Up and Down arrow buttons simultaneously for 5 seconds again
   h) Press hemoglobin (Sp/Hb) button 6 times
   i) “Pr” pulse rate, turn “off” pulse rate by pressing up/down arrow buttons
   j) Press SpHb
   k) “O2” oxygen saturation, turn off oxygen saturation by pressing up/down arrow button
   l) Press SpHb
   m) Press SpHb button again to scroll through other options (do not make other changes without supervisor approval)

1) Connect the RC1 Patient Cable to the Pronto device as shown in the Operator Manual.

2) Connect the Adult or Pediatric Sensor to the RC1 Patient Cable

3) Connecting and Disconnecting Sensor (diagram and instructions below)
To connect the sensor, properly orient the sensor connector (labeled 1) and insert the sensor connector completely into the patient cable connector (labeled 2).

Completely close the protective cover (labeled 3).

Check the remaining number of tests on the sensor on the device prior to the start of monitoring.

To disconnect the sensor, lift the protective cover (labeled 1) to gain access to the sensor connector (labeled 2).

Pull firmly on the sensor connector (labeled 2) to remove from the patient cable (labeled 3). To avoid damage, pull on the sensor connector, not the cable.
Chapter 11. Test Preparation and Performing a Reading

Selecting Child or Adult Sensor

- Measure the participant’s finger size (diameter) at the cuticle, using the sensor size gauge, to determine the correct sensor size. Slide the Slender Digit Gauge circle on the digit as shown in Figure A.
- If the gauge circle stops at any point of the nail bed before the cuticle, the sensor can be used on that digit.
- If the gauge slides past the cuticle as shown in Figure B, the digit is too slender for this sensor. Select a different digit or use a pediatric / slender digit sensor on this patient.

Sensor Site Selection

Remove anything from participant’s arm that can impede blood flow to the sensor site, such as restrictive garments, accessories, purses, backpacks, watches, and jewelry.
- Do not use with an anatomically abnormal finger (e.g. damaged, clubbed, deviated, etc.). Do not use pinkie or index finger.
- You can use the Pronto on sites with nail polish and/or acrylic nails. Some types of nail polish may interfere with the test and prevent a reading, but it is advised to attempt tests with nail polish. Warnings in the user manual alert users that nail polish and acrylics can cause the test to fail due to low SIQ, this results in a test incomplete message.
- If the Pronto displays a result from a site with nail polish, the result is within the specifications for accuracy required by FDA. If a reading fails, it does not reduce the number of tests left on the sensor.
- For Staff: Hand washing or hand sanitizer for staff is required to reduce the transmission of contagious disease.
- For Participants: The use of alcohol wipes on the participant’s finger (or thumb as appropriate) is required to ensure the site is clean and dry prior to testing.
- Select the client’s testing finger in the following priority:
1. Ring or middle finger

2. The thumb may be used instead for children at least 2 years old with very small fingers.

Note: For customer support and to request in-person demonstrations for using the Masimo Pronto contact the Masimo customer service representative Leslie Russell LRussell@masimo.com

**Proper Sensor Conditioning**

Limit movement by securely resting client’s hand and arm with sensor on a horizontal surface. Position hand below heart level to improve circulation and increase perfusion index.

- **Finger Alignment:** Examine the finger while placed in the sensor to ensure the emitter and detector are directly aligned on top of each other and there is no gap between the sensor and fingertip. See figures C and D for proper alignment.

- **Finger Placement:** Make sure fingertip is inserted all the way and touching the finger stop inside the sensor (allowing long finger nails to extend beyond the finger stop).

- **Cable Position:** Run the cable from sensor over the top of the hand without kinks or twists so the cable does not pull on the sensor. See figure E. *Kinks and twists in the cable may increase the time needed to complete tests and cause tests to fail more often.*

- **Participant Instruction:** Instruct client to remain still without any sensor movement. Keep the sensor positioned horizontally.

- **Light Shielding:** Covering the sensor with a hand or cloth will shield the sensor from excessive light. Asking caregivers to cover the hand of children may also help to limit excessive movement during the measurement. *Excessive light may increase the time needed to complete tests and cause tests to fail more often.*
Tips about using the Pronto

- Once the Pronto is activated, it automatically powers off after 1 minute to spare battery power. Turn machine off when not in use to save battery power.
- Fresh batteries (alkaline, non-rechargeable) can be expected to last for approximately 8 hours of use, usually 200-250 tests per battery replacement
- Rechargeable batteries may be used but may need to be replaced more frequently than non-rechargeable alkaline batteries.
- The Pronto cannot be plugged in, it only uses battery power
- Alkaline (non-rechargeable) batteries: When the battery meter display is down to ONE bar, change the batteries. [Note: Recommendation based on Arizona WIC experiences, there is no specific guidance in the manual for when batteries should be replaced.]
- Rechargeable batteries: When battery meter display is down to TWO bars, change the batteries. [Note: Recommendations based on Arizona WIC experiences, there is no specific guidance in the manual for use of rechargeable batteries.]

Tips about the sensors

- Adult and pediatric sized sensors can be used.
- Slender digit guide attached to sensor for selecting appropriately sized sensor (Pediatric/Slender digit sensor is frequently used with women with slender fingers.)
- The finger of a child must be long enough and wide enough to get a reading. The thumb may be used instead for children at least 2 years old with very small fingers.
- Each sensor can be used for a specific number or tests (200, 400, or 1000), display displays the remaining number of tests when powered on
- The sensors DO NOT have a shelf life. They do not expire or become unusable if they have remaining test capacity
- The pediatric sensor has an illustration of “paper dolls” along the side of the sensor
- When the sensor has only 20 tests left the display shows TWO red bars
Performing a Reading

Note: The Pronto will be used to measure hemoglobin for all WIC participants 2 years and older, including adults.

1. Press power button to activate the Pronto.
2. Pronto runs a Self-Test.
3. Pronto will display the number of sensor uses (tests) remaining on the sensor.
4. When the Pronto reads SEN OFF it is ready for testing.
5. Insert selected finger into the sensor to begin testing, you may use the thumb, middle, or ring finger of either hand.
6. Scrolling zeros appear and this indicates sensor initialization.
7. Dashes appear to indicate testing has begun.
8. The letters “PI” (perfusion index) will automatically display after start up in the lower window display. The upper window display will show numerical reading of the PI.
9. Pulse indicator light will flash with each heart beat.
10. It will take 1 to 3 minutes for the Pronto to acquire and display a SpHb measurement.

11. The Spot Check Progress indicator incrementally illuminates from bottom to top and an audible tone will sound when the SpHb measurement is ready to display.
12. Press SpHb button when ready to view SpHb results.
13. SpHb data will display for 5 minutes while the sensor is attached to the finger.

14. After removing the sensor from the finger, SpHb data is available for 5 minutes by depressing either the up or down arrow.

Conducting a Successful Test

**Perfusion Index (PI)** is a numeric indication of the pulse strength at the measurement site:
- Its numerical value ranges between 0.02% and 20%
- Lower values indicate lower perfusion, i.e. cold hands
- PI varies between monitoring sites and from patient to patient, as physiologic conditions vary
- During sensor placement, use sites with higher PI readings for best results
- Monitor the trend of the PI for changes in physiologic conditions

- To successfully conduct a test the “PI” perfusion index must measure 1.0 or greater
- Raise hand to approximately chest level to improve circulation, perfusion index.
- At WIC the Masimo Pronto is only used for children over 2 yrs old
- Tests require participant to remain still until reading is completed
- The device DOES NOT save the readings, be sure to record results immediately
- While testing is in progress a beep will be heard that signals the reading has been taken (complete); press SpHb button after the beep to read HB value
- If the yellow light is on, the test did not work (incomplete)
- It will take 1-3 minutes for the Pronto to acquire an accurate SpHb spot check
- Press SpHb Button when ready to view SpHb results or to perform additional SpHb spot checks
- The Spot Check Progress Indicator incrementally illuminates from bottom to top and an audible tone will sound when the SpHb measurement is ready to display

- Use the Up or Down Arrow to navigate through the parameter and measurement values that have been spot checked
• SpHb data will display for 5 minutes. After 5 minutes, the data can only be obtained by downloading the data through the trend monitor or when another test is performed
Chapter 12. Troubleshooting

Interfering Factors and Troubleshooting

Note: The Masimo Pronto Operator Manual states “inaccurate readings may be caused by: Externally applied coloring (such as nail polish)”. This means that some colors and types of nail polish may slightly affect the reading. Masimo maintains (and an independent study supports) that the most extreme differences observed with nail polish still fall within the performance accuracy range they claim in product specifications. Best practice is to obtain measurements without nail polish, but readings obtained with nail polish are acceptable.

- Acrylic fingernails may sometimes interfere with a successful reading
- Metallic fingernail polish may interfere with reading
- Black or dark purple painted nails may interfere
- Sensor inspections should be done several times a day, debris and grime block sensors (use alcohol wipe)
- Hands dyed with henna, indocyamine green or methylene blue will interfere and make readings inaccurate
- Changes in heart rate cause problems with testing. Choose a relaxed setting where participants are less likely to be stressed
- 4-6% of the population have subclinical issues that will prevent a good reading (carboxyhemoglobin, other irregularities)
- If perfusion index “PI” is less than 1.0, choose another finger

Difficulty or No SpHb Reading

Possible causes include:
- Interference from line frequency induced noise (electrical interference from a coiled or twisted sensor cable, for example)
- Inappropriate sensor
- Excessive motion

Recommendations:
- Ensure there is no coiling of the sensor cable
- Run sensor cable straight up the back of the hand and lower arm
- Verify use of digit gauge to select correct sensor
- Minimize or eliminate motion at the measurement site

Excessive ambient or strobing light

- Shield the sensor from excessive light.
Low Perfusion Index (PI)
Causes and Solutions

<table>
<thead>
<tr>
<th>Causes</th>
<th>Solutions</th>
</tr>
</thead>
</table>
| - Improper sensor type or application
  - Sensor applied too tightly
  - Hypothermia (abnormally low body temperature)
  - Vasoconstriction (narrowing of the blood vessels)
  - Hypovolemia (decreased blood volume)
  - Peripheral Vascular Disease | - Rule out occlusion of blood flow
  - Assure sensor is not attached too tightly
  - Attempt to warm the patient or sensor site
  - Move the sensor to a better perfused site if possible (try another finger or opposite hand) |
### Sensor Fails to Initialize – Circulating LED’s

<table>
<thead>
<tr>
<th>Indication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor is initializing / Determining measurement. Wait for pulse detection. Occurs whenever a spot check is initiated</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Causes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor with exposed components.</td>
<td></td>
</tr>
<tr>
<td>Sensor connected to patient cable and monitor powered on before connecting sensor to patient</td>
<td></td>
</tr>
<tr>
<td>Sensor adjusted to ambient light in room</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Solutions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Always apply sensor to patient prior to connecting to patient cable</td>
<td></td>
</tr>
<tr>
<td>Disconnect and reconnect single patient-use or ReSposable sensor from the patient cable after sensor application</td>
<td></td>
</tr>
<tr>
<td>Shield the sensor from excessive ambient or strobing light</td>
<td></td>
</tr>
</tbody>
</table>

### Low Signal IQ Indicator Troubleshooting Guide

<table>
<thead>
<tr>
<th>Indication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The accuracy of the measurement may be compromised. The SpHb value will not display with Low Signal IQ present unless “Display Low SIQ” is enabled in the Pronto menu.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Causes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper sensor type or application</td>
<td></td>
</tr>
<tr>
<td>Excessive motion or very poor perfusion</td>
<td></td>
</tr>
<tr>
<td>Damaged or non-functional sensor</td>
<td></td>
</tr>
<tr>
<td>Distortion of the sensor/tissue/blood flow interface – either by excessive motion or clinical care</td>
<td></td>
</tr>
<tr>
<td>Ambient Light Interference</td>
<td></td>
</tr>
<tr>
<td>Solutions</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td></td>
</tr>
</tbody>
</table>
| ▪ Assess patient  
▪ Rule out occlusion of blood flow  
▪ Ensure proper sensor application and placement  
▪ Determine if an extreme change in patient’s physiology and blood flow occurred  
▪ Apply Ambient Light Shielding  
▪ Retest after performing above  
▪ Number of SpHb sensor readings available will NOT be reduced when Low SIQ occurs |
Chapter 13. Administration and Maintenance of the Masimo Pronto for the Local Agencies

Administration and Maintenance of Masimo Pronto for the Local Agencies

When to use HemoCue: For all WIC participants requiring hemoglobin measurement between 9 months and less than 2 years of age, the HemoCue analyzer is required.

Cleaning the Pronto

- The Pronto requires cleaning at least once daily, and should be cleaned immediately if you notice debris or grime.
- It is recommended to spray cleanser on a cloth and NOT directly on the Masimo. The outer surface of the Pronto can be cleaned with a soft cloth dampened with soap and a warm water solution.
- Other appropriate cleaning agents include commercial products such as Cidex Plus (3.4% Glutaraldehyde), 0.25% Ammonium Chloride, 70% Isopropyl Alcohol, or by preparing a 10% Bleach solution.
- Do not allow liquids to enter the interior of the Pronto. Do not autoclave, pressure sterilize, or gas sterilize the Pronto.
- Do not soak or immerse the Pronto in any liquid. Do not use petroleum based or acetone solutions, or other harsh solvents to clean the Pronto.

Cleaning Reusable Rainbow Sensors

- Remove the sensor from the patient and disconnect from the patient cable
- Disconnect the patient cable from the device.
- Wipe the entire sensor and / or patient cable clean with 70% Isopropyl alcohol pad.
- Allow to air dry thoroughly before returning it to operation
- To prevent damage, do not soak or immerse in any liquid solution.
- Do not attempt to sterilize by irradiation, steam, autoclave, or ethylene oxide.

Excessive ambient or strobing light

- Shield the sensor from excessive light.

Ordering Equipment, Returns or Replacements
- To order new Pronto machines or to order replacement sensors, please **contact the Masimo customer service representative Leslie Russell LRussell@masimo.com**
- For returns or to replace Masimo machines, please contact your Nutrition Services Consultant.

  Note: The sensors should not be discarded with other disposable waste. When all the loaded tests have been used, sensors are considered electronic waste and should be treated like cell phones and other electronic devices. Please check with your agency about their policy for disposal of electronic waste.

**Receiving a New Pronto**

When receiving a new Masimo machine, please use the instructions in Chapter 10 to initialize the machine for use at WIC. Features such as pulse rate and oxygen saturation are not used in the WIC setting and will be disabled to reduce the use of batteries and sensors for non-WIC purposes.
Appendix A – CDC Cutoffs for Anemia
## Cutoff values for Hemoglobin Levels at 0-2,999 feet

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>action</th>
<th>Pregnant</th>
<th>Breastfeeding/Post-Partum</th>
<th>Infant and Child</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1st Trimester</td>
<td>2nd Trimester</td>
<td>3rd Trimester</td>
</tr>
<tr>
<td>Non-Smoker</td>
<td>Low Hemoglobin</td>
<td>8.6 to 10.9</td>
<td>8.2 to 10.4</td>
<td>8.6 to 10.9</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>8.5 or lower</td>
<td>8.1 or lower</td>
<td>8.5 or lower</td>
</tr>
<tr>
<td>up to 1 pack (1-19 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>8.9 to 11.2</td>
<td>8.4 to 10.7</td>
<td>8.9 to 11.2</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>8.8 or lower</td>
<td>8.3 or lower</td>
<td>8.8 or lower</td>
</tr>
<tr>
<td>1-2 packs (20-39 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>9.6 to 11.4</td>
<td>8.0 to 10.9</td>
<td>9.6 to 11.4</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.5 or lower</td>
<td>7.9 or lower</td>
<td>9.5 or lower</td>
</tr>
<tr>
<td>2+ packs (40+ cigarettes)</td>
<td>Low Hemoglobin</td>
<td>10.3 to 11.6</td>
<td>7.6 to 11.1</td>
<td>10.3 to 11.6</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>10.2 or lower</td>
<td>7.5 or lower</td>
<td>10.2 or lower</td>
</tr>
</tbody>
</table>

Hemoglobin values at or below the "Low Hemoglobin" cutoff are reported as anemic in WIC.
Hemoglobin values in the "Nutritionist" range are referred to a Nutritionist.
### Cutoff values for Hemoglobin Levels at 3,000-3,999 feet

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>action</th>
<th>1st Trimester</th>
<th>2nd Trimester</th>
<th>3rd Trimester</th>
<th>Breastfeeding/Post-Partum</th>
<th>Infant and Child</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0 – 13 weeks</td>
<td>14 – 26 weeks</td>
<td>27 + weeks</td>
<td>12 years to 14 years 11 months</td>
<td>15 years +</td>
</tr>
<tr>
<td>Non-Smoker</td>
<td>Low Hemoglobin</td>
<td>9.1 to 11.1</td>
<td>8.7 to 10.6</td>
<td>9.1 to 11.1</td>
<td>9.5 to 11.9</td>
<td>8.4 to 11.1</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.0 or lower</td>
<td>8.6 or lower</td>
<td>9.0 or lower</td>
<td>9.4 or lower</td>
<td>8.3 or lower</td>
</tr>
<tr>
<td>up to 1 pack (1-19 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>9.4 to 11.4</td>
<td>8.9 to 10.9</td>
<td>9.4 to 11.4</td>
<td>9.8 to 12.2</td>
<td>9.9 to 12.4</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.3 or lower</td>
<td>8.8 or lower</td>
<td>9.3 or lower</td>
<td>9.7 or lower</td>
<td>9.8 or lower</td>
</tr>
<tr>
<td>1-2 packs (20-39 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>10.1 to 11.6</td>
<td>8.5 to 11.1</td>
<td>10.1 to 11.6</td>
<td>10.0 to 12.4</td>
<td>10.4 to 12.6</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>10.0 or lower</td>
<td>8.4 or lower</td>
<td>10.0 or lower</td>
<td>9.9 or lower</td>
<td>10.3 or lower</td>
</tr>
<tr>
<td>2+ packs (40+ cigarettes)</td>
<td>Low Hemoglobin</td>
<td>10.8 to 11.8</td>
<td>8.1 to 11.3</td>
<td>10.8 to 11.8</td>
<td>10.2 to 12.6</td>
<td>10.9 to 12.8</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>10.7 or lower</td>
<td>8.0 or lower</td>
<td>10.7 or lower</td>
<td>10.1 or lower</td>
<td>10.8 or lower</td>
</tr>
</tbody>
</table>

Hemoglobin values at or below the "Low Hemoglobin" cutoff are reported as anemic in WIC.
Hemoglobin values in the "Nutritionist" range are referred to a Nutritionist.
## Cutoff values for Hemoglobin Levels at 4,000-4,999 feet

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>action</th>
<th>Pregnant 1st Trimester 0 – 13 weeks</th>
<th>Pregnant 2nd Trimester 14 – 26 weeks</th>
<th>Pregnant 3rd Trimester 27 + weeks</th>
<th>Breastfeeding/Post-Partum 12 years to 14 years 11 months</th>
<th>Infant and Child Infant 6 to 23 months</th>
<th>Child 2 to 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Smoker</td>
<td>Low Hemoglobin</td>
<td>9.2 to 11.2</td>
<td>8.9 to 10.7</td>
<td>9.2 to 11.2</td>
<td>9.6 to 12.0</td>
<td>9.5 to 12.2</td>
<td>8.5 to 11.2</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.1 or lower</td>
<td>8.8 or lower</td>
<td>9.1 or lower</td>
<td>9.5 or lower</td>
<td>9.4 or lower</td>
<td>8.4 or lower</td>
</tr>
<tr>
<td>up to 1 pack (1-19 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>9.5 to 11.5</td>
<td>9.1 to 11.0</td>
<td>9.5 to 11.5</td>
<td>9.9 to 12.3</td>
<td>10.0 to 12.5</td>
<td>8.8 or lower</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.4 or lower</td>
<td>9.0 or lower</td>
<td>9.4 or lower</td>
<td>9.8 or lower</td>
<td>9.9 or lower</td>
<td></td>
</tr>
<tr>
<td>1-2 packs (20-39 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>10.3 to 11.7</td>
<td>8.7 to 11.2</td>
<td>10.3 to 11.7</td>
<td>10.1 to 12.5</td>
<td>10.5 to 12.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>10.2 or lower</td>
<td>8.6 or lower</td>
<td>10.2 or lower</td>
<td>10.0 or lower</td>
<td>10.4 or lower</td>
<td></td>
</tr>
<tr>
<td>2+ packs (40+ cigarettes)</td>
<td>Low Hemoglobin</td>
<td>11.0 to 11.9</td>
<td>8.3 to 11.4</td>
<td>11.0 to 11.9</td>
<td>10.3 to 12.7</td>
<td>11.0 to 12.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>10.9 or lower</td>
<td>8.2 or lower</td>
<td>10.9 or lower</td>
<td>10.2 or lower</td>
<td>10.9 or lower</td>
<td></td>
</tr>
</tbody>
</table>

Hemoglobin values at or below the "Low Hemoglobin" cutoff are reported as anemic in WIC
Hemoglobin values in the "Nutritionist" range are referred to a Nutritionist
## Cutoff values for Hemoglobin Levels at 5,000-5,999 feet

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>action</th>
<th>Pregnant</th>
<th>Breastfeeding/Post-Partum</th>
<th>Infant and Child</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st Trimester</td>
<td>2nd Trimester</td>
<td>3rd Trimester</td>
<td>12 years to 14 years</td>
</tr>
<tr>
<td>0 – 13 weeks</td>
<td>0 – 13 weeks</td>
<td>14 – 26 weeks</td>
<td>27 + weeks</td>
<td>15 years 6 to 23 months</td>
</tr>
<tr>
<td>Non-Smoker</td>
<td>Low Hemoglobin</td>
<td>9.4 to 11.4</td>
<td>9.0 to 10.9</td>
<td>9.4 to 11.4</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.3 or lower</td>
<td>8.9 or lower</td>
<td>9.3 or lower</td>
</tr>
<tr>
<td>up to 1 pack</td>
<td>Low Hemoglobin</td>
<td>9.7 to 11.7</td>
<td>9.3 to 11.2</td>
<td>9.7 to 11.7</td>
</tr>
<tr>
<td>(1-19 cigarettes)</td>
<td>Nutritionist</td>
<td>9.6 or lower</td>
<td>9.2 or lower</td>
<td>9.6 or lower</td>
</tr>
<tr>
<td>1-2 packs</td>
<td>Low Hemoglobin</td>
<td>10.4 to 11.9</td>
<td>8.9 to 11.4</td>
<td>10.4 to 11.9</td>
</tr>
<tr>
<td>(20-39 cigarettes)</td>
<td>Nutritionist</td>
<td>10.3 or lower</td>
<td>8.8 or lower</td>
<td>10.3 or lower</td>
</tr>
<tr>
<td>2+ packs</td>
<td>Low Hemoglobin</td>
<td>11.1 to 12.1</td>
<td>8.5 to 11.6</td>
<td>11.1 to 12.1</td>
</tr>
<tr>
<td>(40+ cigarettes)</td>
<td>Nutritionist</td>
<td>11.0 or lower</td>
<td>8.4 or lower</td>
<td>11.0 or lower</td>
</tr>
</tbody>
</table>

Hemoglobin values at or below the "Low Hemoglobin" cutoff are reported as anemic in WIC.
Hemoglobin values in the "Nutritionist" range are referred to a Nutritionist.
### Cutoff values for Hemoglobin Levels at 6,000-6,999 feet

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>action</th>
<th>1st Trimester (0 – 13 weeks)</th>
<th>2nd Trimester (14 – 26 weeks)</th>
<th>3rd Trimester (27 + weeks)</th>
<th>Breastfeeding/Post-Partum (12 years to 14 years 11 months)</th>
<th>Infant and Child (Infant 6 to 23 months)</th>
<th>Child (2 to 5 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Smoker</td>
<td>Low Hemoglobin</td>
<td>9.5 to 11.6</td>
<td>9.2 to 11.1</td>
<td>9.5 to 11.6</td>
<td>10.0 to 12.4</td>
<td>9.8 to 12.6</td>
<td>8.8 to 11.6</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.4 or lower</td>
<td>9.1 or lower</td>
<td>9.4 or lower</td>
<td>9.9 or lower</td>
<td>9.7 or lower</td>
<td>8.7 or lower</td>
</tr>
<tr>
<td>up to 1 pack (1-19 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>9.8 to 11.9</td>
<td>9.4 to 11.4</td>
<td>9.8 to 11.9</td>
<td>10.3 to 12.7</td>
<td>10.3 to 12.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.7 or lower</td>
<td>9.3 or lower</td>
<td>9.7 or lower</td>
<td>10.2 or lower</td>
<td>10.2 or lower</td>
<td></td>
</tr>
<tr>
<td>1-2 packs (20-39 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>10.6 to 12.1</td>
<td>9.0 to 11.6</td>
<td>10.6 to 12.1</td>
<td>10.5 to 12.9</td>
<td>10.8 to 13.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>10.5 or lower</td>
<td>8.9 or lower</td>
<td>10.5 or lower</td>
<td>10.4 or lower</td>
<td>10.7 or lower</td>
<td></td>
</tr>
<tr>
<td>2+ packs (40+ cigarettes)</td>
<td>Low Hemoglobin</td>
<td>11.3 to 12.3</td>
<td>8.6 to 11.8</td>
<td>11.3 to 12.3</td>
<td>10.7 to 13.1</td>
<td>11.3 to 13.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>11.2 or lower</td>
<td>8.5 or lower</td>
<td>11.2 or lower</td>
<td>10.6 or lower</td>
<td>11.2 or lower</td>
<td></td>
</tr>
</tbody>
</table>

Hemoglobin values at or below the "Low Hemoglobin" cutoff are reported as anemic in WIC. Hemoglobin values in the "Nutritionist" range are referred to a Nutritionist.
### Cutoff values for Hemoglobin Levels at 7,000-7,999 feet

<table>
<thead>
<tr>
<th>Smoking Status</th>
<th>action</th>
<th>Pregnant</th>
<th>Breastfeeding/Post-Partum</th>
<th>Infant and Child</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1st Trimester</td>
<td>2nd Trimester</td>
<td>3rd Trimester</td>
</tr>
<tr>
<td>Non-Smoker</td>
<td></td>
<td>0 – 13 weeks</td>
<td>14 – 26 weeks</td>
<td>27 + weeks</td>
</tr>
<tr>
<td>Low Hemoglobin</td>
<td>Nutritionist</td>
<td>9.7 to 11.9</td>
<td>9.4 to 11.4</td>
<td>9.7 to 11.9</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.6 or lower</td>
<td>9.3 or lower</td>
<td>9.6 or lower</td>
</tr>
<tr>
<td>up to 1 pack (1-19 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>10.0 to 12.2</td>
<td>9.6 to 11.7</td>
<td>10.0 to 12.2</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>9.9 or lower</td>
<td>9.5 or lower</td>
<td>9.9 or lower</td>
</tr>
<tr>
<td>1-2 packs (20-39 cigarettes)</td>
<td>Low Hemoglobin</td>
<td>10.7 to 12.4</td>
<td>9.2 to 11.9</td>
<td>10.7 to 12.4</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>10.6 or lower</td>
<td>9.1 or lower</td>
<td>10.6 or lower</td>
</tr>
<tr>
<td>2+ packs (40+ cigarettes)</td>
<td>Low Hemoglobin</td>
<td>11.4 to 12.6</td>
<td>8.8 to 12.1</td>
<td>11.4 to 12.6</td>
</tr>
<tr>
<td></td>
<td>Nutritionist</td>
<td>11.3 or lower</td>
<td>8.7 or lower</td>
<td>11.3 or lower</td>
</tr>
</tbody>
</table>

Hemoglobin values at or below the "Low Hemoglobin" cutoff are reported as anemic in WIC. Hemoglobin values in the "Nutritionist" range are referred to a Nutritionist.
Appendix B – Very Low Hemoglobin Values

Very low hemoglobin values:
A very low hemoglobin level is a serious medical concern and is life-threatening. Local Agencies shall 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 shall be documented in HANDS.

Table of Very Low Hemoglobin Values

<table>
<thead>
<tr>
<th>Altitude</th>
<th>Hemoglobin Reading (&lt;g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2,999 (sea level)</td>
<td>6.5</td>
</tr>
<tr>
<td>3000-3999</td>
<td>6.7</td>
</tr>
<tr>
<td>4000-4999</td>
<td>6.8</td>
</tr>
<tr>
<td>5000-5999</td>
<td>7.0</td>
</tr>
<tr>
<td>6000-6999</td>
<td>7.2</td>
</tr>
<tr>
<td>7000-7999</td>
<td>7.5</td>
</tr>
<tr>
<td>8000-8999</td>
<td>7.8</td>
</tr>
<tr>
<td>9000-9999</td>
<td>7.8</td>
</tr>
<tr>
<td>10,000 – 11,000</td>
<td>7.9</td>
</tr>
</tbody>
</table>

Cigarette Smoking – add to cut off value

<table>
<thead>
<tr>
<th>Cigarette Smoking</th>
<th>Cut off Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 - &lt; 1.0 pack per day</td>
<td>+0.3</td>
</tr>
<tr>
<td>1.0 - &lt; 2.0 packs per day</td>
<td>+0.5</td>
</tr>
<tr>
<td>≥2.0 packs per day</td>
<td>+0.7</td>
</tr>
<tr>
<td>All smokers</td>
<td>+0.3</td>
</tr>
</tbody>
</table>
Appendix C – 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 the WIC Nutrition Consultant.

**Masimo Pronto Technical Support**
To order new Pronto machines or to order replacement sensors, please contact the Masimo customer service representative Leslie Russell LRussell@masimo.com

For returns or to replace Masimo machines, please contact your Nutrition Services Consultant.
# Appendix D – HemoCue® Hb 201⁺ System Maintenance Log

## HemoCue® Hb 201⁺ System Maintenance Log

Analyzer Serial Number _______________________

<table>
<thead>
<tr>
<th>DATE</th>
<th>PROBLEM</th>
<th>CORRECTIVE ACTION</th>
<th>INITIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix E – HemoCue Trouble Shooting Guide
## 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.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Explanation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The analyzer shows an error code.</td>
<td>May be a temporary fault.</td>
<td>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.</td>
</tr>
<tr>
<td>E00</td>
<td>No stable endpoint is found within the time range. 1. The cuvette is faulty. 2. The circuit board is out of order.</td>
<td>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.</td>
</tr>
<tr>
<td>E01–E05</td>
<td>1. Dirty optronic unit or faulty electronic or optronic unit.</td>
<td>1a. Turn off the analyzer and clean the optronic unit as described in the maintenance section. 1b. The analyzer needs service. Contact HemoCue, Inc.</td>
</tr>
<tr>
<td>E06</td>
<td>1. Unstable blank value. The analyzer might be cold.</td>
<td>1. Turn off the analyzer and allow it to reach room temperature. If the problem continues, the analyzer needs service. Contact HemoCue, Inc.</td>
</tr>
<tr>
<td>E07</td>
<td>1. The battery power is too low.</td>
<td>1a. The batteries need to be replaced. Turn off the analyzer and replace the batteries, 4 type AA. 1b. Use the power adapter.</td>
</tr>
<tr>
<td>E08</td>
<td>The absorbance is too high. 1. An item is blocking the light in the cuvette holder.</td>
<td>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.</td>
</tr>
<tr>
<td>E09–E30</td>
<td>1. Dirty optronic unit or faulty electronic or optronic unit.</td>
<td>1a. Turn off the analyzer and clean the optronic unit as described in the maintenance section. 1b. The analyzer needs service. Contact HemoCue, Inc.</td>
</tr>
<tr>
<td>Symptom</td>
<td>Explanation</td>
<td>Action</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>HHH</td>
<td>1. Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L).</td>
<td>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. 2. Turn off the analyzer and replace the batteries, 4 type AA. 3. The analyzer needs service. Contact HemoCue, Inc.</td>
</tr>
<tr>
<td>No characters on the display</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>The display gives erroneous characters.</td>
<td>1. The display is out of order. 2. The microprocessor is out of order.</td>
<td>1. The analyzer needs service. Contact HemoCue, Inc. 2. The analyzer needs service. Contact HemoCue, Inc.</td>
</tr>
<tr>
<td>The display shows “□□”.</td>
<td>1. The batteries need to be replaced. 2. If on mains power, the mains adapter or the circuit board is out of order.</td>
<td>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.</td>
</tr>
<tr>
<td>The display does not switch from “□□” and “□” (read for measuring).</td>
<td>1. The magnet in the cuvette holder may be missing. 2. The magnetic sensor is out of order.</td>
<td>1. The analyzer needs service. Contact HemoCue, Inc. 2. The analyzer needs service. Contact HemoCue, Inc.</td>
</tr>
<tr>
<td>Measurements on patient samples are higher or lower than anticipated.</td>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>
Appendix F – CLIA Application for Certification

http://www.azdhs.gov/lab/license/certification/applications.htm
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Initial Application</th>
<th>Survey</th>
<th>CLIA IDENTIFICATION NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in Certificate Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Closure/Other Changes (Specify)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effective Date</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(If an initial application leave blank, a number will be assigned)

<table>
<thead>
<tr>
<th>FACILITY NAME</th>
<th>FEDERAL TAX IDENTIFICATION NUMBER</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>EMAIL ADDRESS</th>
<th>TELEPHONE NO. (Include area code)</th>
<th>FAX NO. (Include area code)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable). Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified

<table>
<thead>
<tr>
<th>MAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon or certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>NUMBER, STREET (No P.O. Boxes)</th>
<th>NUMBER, STREET</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CITY</th>
<th>STATE</th>
<th>ZIP CODE</th>
<th>CITY</th>
<th>STATE</th>
<th>ZIP CODE</th>
</tr>
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<tbody>
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</tbody>
</table>

SEND CERTIFICATE TO THIS ADDRESS

<table>
<thead>
<tr>
<th>Physical</th>
<th>Mailing</th>
<th>Corporate</th>
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<tbody>
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</tbody>
</table>

SEND FEES COUPON TO THIS ADDRESS

<table>
<thead>
<tr>
<th>Physical</th>
<th>Mailing</th>
<th>Corporate</th>
</tr>
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<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

CORPORATE ADDRESS (If different from facility address) send Fee Coupon or certificate

<table>
<thead>
<tr>
<th>NUMBER, STREET</th>
<th>CITY</th>
<th>STATE</th>
<th>ZIP CODE</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

NAME OF DIRECTOR (Last, First, Middle Initial)

<table>
<thead>
<tr>
<th>CREDENTIALS</th>
<th>FOR OFFICE USE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date Received</td>
</tr>
</tbody>
</table>

II. TYPE OF CERTIFICATE REQUESTED ((Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

- [ ] Certificate of Waiver (Complete Sections I – VI and IX – X)
- [ ] Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – X)
- [ ] Certificate of Compliance (Complete Sections I – X)
- [ ] Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.
  - The Joint Commission
  - AOA
  - AABB
  - CAP
  - COLA
  - ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.
III. TYPE OF LABORATORY (Check the one most descriptive of facility type)

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

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format. If testing 24/7, check here)

<table>
<thead>
<tr>
<th></th>
<th>SUNDAY</th>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
<th>SATURDAY</th>
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</thead>
<tbody>
<tr>
<td>FROM:</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>TO:</td>
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</tbody>
</table>

(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 in 1-3 below)

Are you applying for a single site CLIA certificate to cover multiple testing locations?
- 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 is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as a mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?
   - Yes [ ]
   - No [ ]

   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

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

<table>
<thead>
<tr>
<th>NAME OF LABORATORY OR HOSPITAL DEPARTMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDRESS/LOCATION (Number, Street, Location if applicable)</td>
</tr>
<tr>
<td>CITY, STATE, ZIP CODE</td>
</tr>
<tr>
<td>TELEPHONE NO. (Include area code)</td>
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</table>

TESTS PERFORMED/SPECIALTY/SUBSPECIALTY

<table>
<thead>
<tr>
<th>NAME OF LABORATORY OR HOSPITAL DEPARTMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDRESS/LOCATION (Number, Street, Location if applicable)</td>
</tr>
<tr>
<td>CITY, STATE, ZIP CODE</td>
</tr>
<tr>
<td>TELEPHONE NO. (Include area code)</td>
</tr>
</tbody>
</table>
In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING
Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.
  e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed

☐ Check if no waived tests are performed

VII. PPM TESTING
Identify the PPM testing (to be) performed. Be as specific as possible.
  e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the “total estimated annual test volume” in section VIII.

☐ Check if no PPM tests are performed

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

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Accreditation)*
If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

<table>
<thead>
<tr>
<th>SPECIALTY / SUBSPECIALTY</th>
<th>ACCREDITING ORGANIZATION</th>
<th>ANNUAL TEST VOLUME</th>
<th>SPECIALTY / SUBSPECIALTY</th>
<th>ACCREDITING ORGANIZATION</th>
<th>ANNUAL TEST VOLUME</th>
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<tr>
<td>HISTOCOMPATIBILITY 010</td>
<td></td>
<td>HEMATOLOGY 400</td>
<td></td>
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<tr>
<td>☐ Transplant</td>
<td></td>
<td></td>
<td>☐ Homatology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Nontransplant</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>MICROBIOLOGY</td>
<td></td>
<td></td>
<td>IMMUNOHEMATOLOGY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Bacteriology 110</td>
<td></td>
<td></td>
<td>☐ Antibody Detection (transfusion) 520</td>
<td>ABO Group &amp; Rh Group 510</td>
<td></td>
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<tr>
<td>☐ Mycobacteriology 115</td>
<td></td>
<td></td>
<td>☐ Antibody Detection (nontransfusion) 530</td>
<td></td>
<td></td>
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<tr>
<td>☐ Mycology 120</td>
<td></td>
<td></td>
<td>☐ Antibody Identification 540</td>
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<td></td>
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<tr>
<td>☐ Parasitology 130</td>
<td></td>
<td></td>
<td>☐ Compatibility Testing 550</td>
<td></td>
<td></td>
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<tr>
<td>☐ Virology 140</td>
<td></td>
<td></td>
<td>PATHOLOGY</td>
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<tr>
<td>DIAGNOSTIC IMMUNOLOGY</td>
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<td></td>
<td>☐ Histopathology 610</td>
<td></td>
<td></td>
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<tr>
<td>☐ Syphilis Serology 210</td>
<td></td>
<td></td>
<td>☐ Oral Pathology 620</td>
<td></td>
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<tr>
<td>☐ General Immunology 220</td>
<td></td>
<td></td>
<td>☐ Cytology 630</td>
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<tr>
<td>CHEMISTRY</td>
<td></td>
<td>RADIOBIOASSAY 800</td>
<td></td>
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<tr>
<td>☐ Routine 310</td>
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<td></td>
<td>☐ Radiobioassay</td>
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<tr>
<td>☐ Urinalysis 320</td>
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<td>CLINICAL CYTOGENETICS 900</td>
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<td>☐ Endocrinology 330</td>
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<td></td>
<td>☐ Clinical Cytogenetics</td>
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<tr>
<td>☐ Toxicology 340</td>
<td></td>
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</tr>
</tbody>
</table>

TOTAL ESTIMATED ANNUAL TEST VOLUME:
IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT  FOR PROFIT  GOVERNMENT

01 Religious Affiliation  04 Proprietary  05 City
02 Private Nonprofit  06 County  07 State
03 Other Nonprofit  08 Federal  09 Other Government
(Specify)  (Specify)  (Specify)

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:

<table>
<thead>
<tr>
<th>CLIA NUMBER</th>
<th>NAME OF LABORATORY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

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 (Sign in Ink)  DATE

NOTE: Completed 116 applications must be sent to your local State Agency.

SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. The time required to complete this information collection is estimated to average 30 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.
THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory’s operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility’s laboratory operation. All information submitted should be based on your facility’s laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training, and experience under subpart M (42 CFR PART 493) of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application. Information to be submitted with the application include:

- Verification of State Licensure, as applicable
- Documentation of qualifications:
  - Education (copy of Diploma, transcript from accredited institution, CMEs),
  - Credentials, and
  - Laboratory experience.

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check “initial application”. For an initial survey or for a recertification, check “survey”. For a request to change the type of certificate, check “change in certificate type” and provide the effective date of the change. For all other changes, including change in location, director, lab closure, etc., check “closure/other changes” and provide the effective date of the change.

CLIA Identification Number: For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. For all other applicants, enter the 10 digit CLIA identification number already assigned and listed on your CLIA certificate.

Facility Name: Be specific when indicating the name of your facility, particularly when it is a component of a larger entity, e.g., respiratory therapy department in XYZ Hospital. For a physician’s office, this may be the name of the physician. NOTE: the information provided is what will appear on your certificate.

Physical Facility Address: This address is mandatory and must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

If the laboratory has a separate mailing and/or corporate address (from the Facility Address), please complete the appropriate sections on the form.

Mailing Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to an alternate location, such as an accounts payable office. A Post Office box number or Mail Stop number may be used as part of the Mailing Address for this section.

Corporate Address: This address is optional and may be used if the laboratory wants to direct the mailing of the CLIA fee coupon and/or CLIA certificate to another location, such as, the main headquarters or home office for the laboratory. A Post Office box number or Mail Stop number may be used as part of the Corporate Address for this section.

Form Mailing: Select the address (Physical, Mailing, Corporate) where the CLIA fee coupon and CLIA certificate are to be mailed.

For Office Use Only: The date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

Select your certificate type based on the highest level of test complexity performed by your laboratory. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory.

When completing this section, please remember that a facility holding a Certificate of Waiver can only perform tests categorized as waived;
• Certificate for Provider Performed Microscopy Procedures (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*

• Certificate of Compliance can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met following a CLIA survey; and

• Certificate of Accreditation can perform tests categorized as waived, PPM and moderate and/or high complexity non-waived tests provided the laboratory is currently accredited by an approved accreditation organization. (If your CMS-approved accreditation organization is not listed, contact your local State Agency for further instructions.)

*A current list of waived and PPM tests may be obtained from your State agency. Specific test system categorizations can also be found on the Internet at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm.

III. TYPE OF LABORATORY
Select the type that is most descriptive of the location where the laboratory testing is performed.

If selecting ‘mobile laboratory’ (code 19), a mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. For record keeping purposes, include, on a separate sheet of paper, the vehicle identification numbers (VINS) of all vehicles used for mobile laboratory testing.

If selecting ‘physician office’ (code 21), also answer a related question regarding ‘shared labs’.

A shared laboratory is when two or more sole practicing physicians collectively pool resources to fund one laboratory’s operations. The definition of a shared laboratory may also include two or more physician group practices that share the expenses for the laboratory’s operation.

If selecting ‘Practitioner Other’ (code 22), this type includes practitioners such as, dentists, chiropractors, etc.

IV. HOURS OF ROUTINE OPERATION
Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format and check box marked ‘24/7’ if laboratory testing is performed continuously, e.g., 24 hours a day, 7 days a week. Do not use military time.

V. MULTIPLE SITES
You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3) Hospice and HHA could qualify for an exception.

VI. WAIVED TESTING
Indicate the estimated total annual test volume for all waived tests performed. List can be found at: http://www.cms.gov/CLIA/downloads/waivetbl.pdf

VII. PPM TESTING
Indicate the estimated total annual test volume for all PPM tests performed. List can be found at: http://www.cms.gov/CLIA/downloads/ppmp.list.pdf

VIII. NON-WAIVED TESTING (INCLUDING PPM)
The total Estimated Annual Test volume in this section includes all non-waived tests, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section for test counting information. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL
Select the type of ownership or control which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES
List all other facilities for which the director is responsible and that are under different certificates. Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.
CHEMISTRY
Routine Chemistry (310)
Albumin
Ammonia
Alk Phos
ALT/SGPT
AST/SGOT
Amylase
Bilirubin
Blood gas (pH, pO2, pCO2)
BUN
Calcium
Chloride
Cholesterol
Cholesterol, HDL
CK/CK isoenzymes
CO2
Creatinine
Ferritin
Folate
GGT
Glucose (Not fingerstick)
Iron
LDH/LDH isoenzymes
Magnesium
Potassium
Protein, electrophoresis
Protein, total
PSA
Sodium
Triglycerides
Troponin
Uric acid
Vitamin B12

Toxicology (340)
Acetaminophen
Blood alcohol
Blood lead (Not waived)
Carbamazepine
Digoxin
Ethisuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procanamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Therapeutic Drug Monitoring

Urinalysis** (320)
Automated Urinalysis (Not including waived instruments)
Microscopic Urinalysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfosalicylic acid
** Dipstick urinalysis is counted in Section VI. WAIVED TESTING

Endocrinology (330)
Cortisol
HCG (serum pregnancy test)
T3
T3 Uptake
T4
T4, free
TSH

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.

- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.

- For **general immunology**, testing for allergens should be counted as one test per individual allergen.

- For **hematology**, each measured individual analyte of a complete blood count or flow cytometry test that is ordered and reported is counted separately. The **WBC differential** is counted as one test.

- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.

- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.

- For **cytology**, each slide (not case) is counted as one test for both Pap smears and non-gynecologic cytology.

- For **clinical cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.

- For **chemistry**, each analyte in a profile counts as one test.

- For **urinalysis**, microscopic and macroscopy examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.

- For all specialties/subspecialities, do not count calculations (e.g., A/G ratio, MCH, T7, etc.), quality control, quality assurance, or proficiency testing assays.

If you need additional information concerning counting tests for CLIA, please contact your State agency.