ARIZONA
DEPARTMENT OF HEALTH SERVICES
BUREAU OF NUTRITION
& PHYSICAL ACTIVITY

LABORATORY PROCEDURE MANUAL

Contents

Chapter 1. Introduction

Purpose

This manual is designed to be used as a reference tool to help WIC staff safely and accurately perform hemoglobin tests. Use the hyperlinks in the Table of Contents above to quickly locate the information needed.

Anemia and Hemoglobin Testing

The Arizona WIC Program conducts hemoglobin testing on its participants as a screening tool for anemia, which is a condition resulting from low levels of healthy red blood cells. Its symptoms include poor appetite, tiredness, weakness, developmental delays and learning problems. Iron deficiency anemia is the most common type of anemia, and represents a significant global health concern.

The hemoglobin tests performed within Arizona WIC clinics cannot be used to diagnose anemia or a specific type of anemia without follow up testing by a health care provider. However, the results of hemoglobin tests obtained at WIC are an effective way to identify participants most likely to benefit from participant education and community healthcare referrals.

Types of Hemoglobin Testing

The Arizona WIC Program utilizes two different types of hemoglobin tests. The Masimo Pronto is a non-invasive hemoglobin testing device that is required to be used on WIC participants aged 2 years and older. Capillary sampling is the other, more invasive type of hemoglobin testing completed within the Arizona WIC program, and is only designed to be used on participants under the age of 2, but can be used on participants over the age of 2 if no hemoglobin value is able to be obtained with the Masimo Pronto. Capillary sampling involves taking a small sample of a participant's blood, and measuring the amount of hemoglobin it contains using a hemoglobin analyzer. We'll discuss both types of hemoglobin tests in future chapters of this manual.

Individual and Local Agency Hematology Training Requirements

In order for CPAs to complete unsupervised hemoglobin blood tests within Arizona WIC clinics, it's mandatory that they:

- Complete the Hemoglobin LMS course, and pass the corresponding post-test
- Complete the Hemoglobin Guidebook, and discuss their answers with their local agency trainer
- Complete the required Hematology observations as indicated in the New Employee Training Plan

In addition to these individual requirements, each local agency must also designate one or more trainers to provide hematology training and observations with staff. Local agencies must also receive and maintain a CLIA Laboratory Certification in order to complete hemoglobin tests. Visit Appendix G of this manual to review the procedures for obtaining a CLIA Laboratory Certification.

Chapter 2. Universal / Standard Precautions

Universal Precautions

The umbrella term "Universal Precautions" refers to approaches to minimize occupational exposure to bloodborne pathogens. A key component of taking Universal Precautions is to treat the blood and bodily fluid of others as if it contained a bloodborne pathogen such as Human Immuno-deficiency Virus (HIV), Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV), regardless if the person has a known or suspected bloodborne pathogen.

There are 2 types of universal precautions: "Standard Precautions" and "Transmission-Based Precautions".

1. **Standard Precautions** are a basic set of precautions that need to be taken whenever coming into potential contact with blood or other bodily fluids.
2. **Transmission-Based Precautions** are steps that should be taken in addition to "Standard Precautions" if the person you're coming into contact with has a known or suspected condition that can be spread through the air (e.g. chickenpox), through droplets from coughs or sneezes (e.g. influenza) or by coming into contact with the skin (e.g. herpes simplex virus).

There are four main components of Standard Precautions that are required to be followed in all Arizona WIC clinics:

1. Hand Hygiene
2. Personal Protective Equipment
3. Sharps Safety
4. Cleaning and Disinfection

We'll discuss each of these topics in the following sections of this chapter.

Transmission-Based Precautions will not be discussed in this document. Speak with your supervisor if you ever believe that additional Transmission-Based Precautions are necessary in order to protect your health and safety.

Standard Precautions (Hand Hygiene)

The Centers for Disease Control and Prevention (CDC) defines Hand Hygiene as "Cleaning your hands using either handwashing (washing hands with soap and water), antiseptic hand wash, antiseptic hand rub (i.e. alcohol-based hand sanitizer including foam or gel), or surgical hand antisepsis." In the WIC program, there are two methods generally used for hand hygiene: alcohol-based hand sanitizer and washing hands with soap and water. The table below describes examples of when each is recommended. Source: CDC

Alcohol-Based Hand Sanitizer vs Soap and Water

When to Use Alcohol-Based Hand Sanitizer 	When to Wash with Soap and Water 
Immediately before touching a patient	When hands are visibly soiled
Before moving from work on a soiled body site to a clean body site on the same patient	After caring for a person with known or suspected infectious diarrhea
After touching a patient or the patient's immediate environment	After known or suspected exposure to spores (e.g. B. anthracis, C difficile outbreaks)
After contact with blood, body fluids, or contaminated surfaces	
Immediately after glove removal	

Source: CDC

How to Use Alcohol-Based Hand Sanitizer:

- Apply the amount of product recommended by the manufacturer in your hands.
- Continuously rub the product over all parts of your hands until your hands feel dry (approximately 20 seconds).

How to Wash Hands with Soap and Water:

- Wet your hands first.
- Apply the amount of product recommended by the manufacturer in your hands, and vigorously rub it over all parts of your hands for at least 20 seconds.
- Rinse your hands with water, and dry them with disposable towels. Use a disposable towel to turn off the water.

Source: CDC

Standard Precautions (Personal Protection Equipment)

Wearing personal protection equipment (PPE) is essential in order to help protect your safety, and the safety of others while working in the lab and must be worn whenever it can be reasonably assumed that contact with blood or other potentially infectious materials may occur. Gloves are by far the most common form of PPE used in WIC clinics, so they

are the only form of PPE discussed in this manual. However, you must wear additional forms of PPE (e.g. gloves, masks, goggles, face shields etc.) if required by your local agency's policies. Gloves provide an additional layer of protection, helping to stop the possible spread of infection from the wearer and others. However, wearing gloves should never replace hand hygiene.

At WIC, gloves should be worn in the following situations:

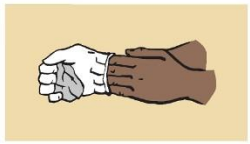
- **Before beginning a capillary sampling test**: When starting to perform a capillary sampling test, perform hand hygiene and cover any breaks in the skin with bandages before applying gloves.
- **Between capillary sampling tests:** Change gloves in between capillary sampling tests, even if performing the tests on members of the same family.
- **Damaged or defective gloves:** Immediately change gloves and perform hand hygiene if gloves show defects or ever become damaged while performing a capillary sampling test.
- **Soiled gloves:** If gloves become visibly soiled with blood or other body fluids, carefully remove gloves, and perform hand hygiene after completing the capillary sampling test.

To remove gloves, take the following steps:

1. Using a gloved hand, pinch the palm area of the other gloved hand and peel off the first glove.


2. Using the gloved hand only, roll-up the removed glove into a ball, and hold it in the palm of the gloved hand.

3. Using your ungloved hand, slide a finger under your gloved hand and peel off the second glove over the first rolled-up glove.




4.Discard both gloves in the waste container designated by your local agency.

Source: CDC

Standard Precautions (Sharps Safety)

Retractable lancets are used during capillary sampling tests. Even though retractable lancets contain safety features (e.g. retractable needles) that help to prevent the user from accidental needle sticks, it's still important to take safety precautions. These include:

Focusing on the task at hand

- Keeping fingers away from the opening of the lancet
- Immediately disposing of used lancets and microcuvettes in a "sharps" container.

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.

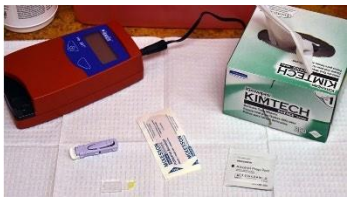
When this container is filled to the acceptable level, it must be properly disposed of as biohazardous waste.

Standard Precautions (Cleaning and Disinfection)

There are different receptacles for trash that is generated in the lab.

Sharps container

- Lancets and microcuvettes must be disposed of in sharps containers.



- Throw away trash that is saturated with blood in a red, plastic biohazard bag. All waste that is saturated and dripping with blood must be, sterilized, incinerated or, chemically disinfected prior to mixing and disposing with ordinary waste. Find out from your supervisor how to handle biohazardous waste since it must be decontaminated before it can be disposed of in a landfill.
- Waste, such as lint-free tissue, alcohol preps, gloves, bandages & wrappers, that contain blood but are not dripping, can be discarded in a regular trash bag if there are no means for biohazard waste disposal.

- It's important that all lab work surfaces are cleaned thoroughly at least once a day, but also must be cleaned immediately if they are visibly soiled. Lab work surfaces must be cleaned using either a 10% bleach solution or a disinfectant approved for use in your local agency.
- 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. The expiration date is seven calendar days after the date the solution was prepared.

Note: Keep the sharps container, biohazard bag, lab trash, and all cleaning products out of the reach of children.

Exposure Control Plan

A written exposure control plan must be kept in an easily accessible location at each WIC clinic. The plan in your clinic will include a copy of your local agencies' policies and procedures for employee safety and a procedure for reporting accidents. Speak with your supervisor to ensure that you know where to locate the exposure control plan in your clinic, and familiarize yourself with its contents.

If blood touches your skin or hair, wash the area with soap and water immediately.

- If blood enters your eye(s), flush them with water immediately.
- If you are accidentally stuck by a used lancet, have blood touch your skin/hair, have blood enter your eye(s), or if you have any reason to believe that you may have been exposed to an infectious substance, notify your supervisor immediately to discuss seeing a licensed healthcare provider to be tested for infectious diseases such as HIV, HBV, and HCV.

Chapter 3. Capillary Sampling Equipment

Lancets

Lancets are small, single-use devices that are designed to pierce the skin, allowing a blood sample to be collected with a microcuvette. There are various lancets available depending on incision depth and intended puncture location (e.g. finger or heel). Check with local agency trainers / supervisors to ensure that the correct lancets are used based on differing situations. In addition, refer to the chart below for lancet requirements for each WIC participant category.

Choosing the correct lancet size

Infants certified at less than 9 months old

- Finger Puncture Depth: n/a
- Heel Puncture Depth: n/a

Infants certified from 9-11 months

- Finger Puncture Depth: 1.5 mm or less
- Heel Puncture Depth: 2.0 mm or less.*
  *May only be performed on infants who have not yet begun to learn to walk.

Children (1 to 5 years)

- Finger Puncture Depth: 1.5 mm or less
- Heel Puncture Depth: n/a

Women (Pregnant / Postpartum / Breastfeeding)

- Finger Puncture Depth: 2.4 mm or less
- Heel Puncture Depth: n/a

Microcuvettes

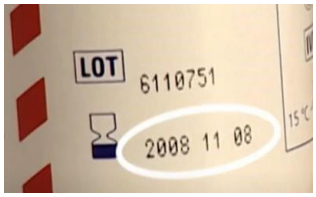
Microcuvettes are manufactured to be used only in the hemoglobin analyzer for which they were designed. Therefore, only use the microcuvettes designed for the hemoglobin analyzer(s) used in your local agency clinic.

HemoCue 201+ Microcuvettes and Microcuvette container

HemoCue 201+ Microcuvette

HemoCue 201+ Microcuvette Container

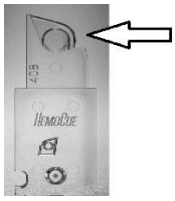
HemoCue 201 Microcuvettes contain a special reagent designed to work inside of the HemoCue 201+ which is noticeable due to its yellow color at the tip of each microcuvette (see picture).



Once the vial of HemoCue 201+ Microcuvettes has been opened, they are able to be used up to 90 days afterwards.

- Upon opening a vial for the first time, write the date the vial was opened, as well as the date that the microcuvettes must be used by on the side of the vial.
- Always use microcuvettes by the expiration date written on the side of the each vile, regardless of whether the vial has been opened or not.

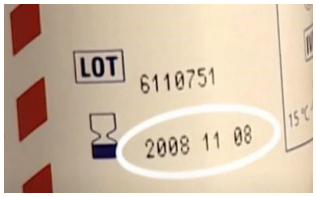
HemoCue 301 Microcuvettes



HemoCue 301 Microcuvette with colorless tip

HemoCue 301 Microcuvette Vial

Unlike HemoCue 201+ Microcuvettes, HemoCue 301+ Microcuvettes do not contain any reagent, so their tips are completely clear (see picture).



The HemoCue 301 Microcuvettes are able to be used up to the expiration date printed on the microcuvette vial, typically 24 months from the date of manufacture.

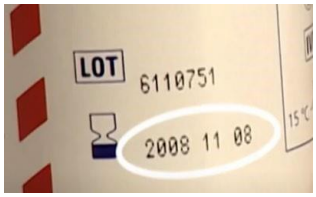
- **Upon opening a vial for the first time:** Write the date the vial was opened, as well as the date that the microcuvettes must be used by on the side of the vial.
- **Always use microcuvettes by the expiration date written on the side of the each vial**, regardless of whether the vial has been opened or not.

HemoCue 801 Microcuvettes

HemoCue 801 Microcuvette with colorless tip

HemoCue 801 Microcuvette Vial

Unli8HemoCue 801 Microcuvettes do not contain any reagent, so their tips are completely clear (see picture).

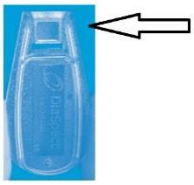


The HemoCue 801 Microcuvettes are able to be used up to the expiration date printed on the microcuvette vial, typically 24 months from the date of manufacture.

- **Upon opening a vial for the first time:** Write the date the vial was opened, as well as the date that the microcuvettes must be used by on the side of the vial.
- **Always use microcuvettes by the expiration date written on the side of the vial**, regardless of whether the vial has been opened or not.

McKesson Consult Microcuvettes

Package of McKesson Consult Microcuvettes



McKesson Consult Microcuvette with colorless tip

McKesson Consult Microcuvettes do not contain any reagent, so their tips are completely clear (see picture).

Use microcuvettes for the McKesson Consult prior the expiration date printed on the package regardless of whether the package has been opened or not.

Hemoglobin Analyzers

The purpose of hemoglobin analyzers is to measure the amount of hemoglobin contained in a blood sample. The Arizona WIC Program utilizes 3 different types of Hemoglobin Analyzers: HemoCue 201+, HemoCue 301, and McKesson Consult.

HemoCue 201+

The HemoCue 201+ hemoglobin analyzer is a portable instrument with a sliding cuvette holder and display screen. It can operate on AC power (AC adapter included) or 4 AA batteries.

HemoCue 201+ Cuvette Holder Cleaning

Clean cuvette holder after each day of use by following these steps:

Above: Cuvette Holder in Open Position

1. Turn off the analyzer. Pull the cuvette holder out to the loading position.

2. While pressing the catch carefully pull out the cuvette holder.

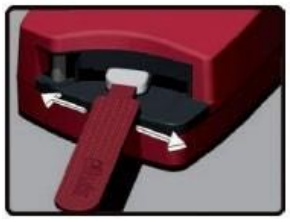
3. Remove the cuvette holder from the analyzer. It will come off of the stainless steel pin it rotates on.

4. Clean the cuvette holder with alcohol (20-70%) or mild detergent.
5. Wait 15 minutes to air dry before replacing the cuvette holder (making sure that it's locked in place by the catch) and using the HemoCue 201+.

HemoCue 201+ Optical Parts Cleaning

The optronic unit inside the HemoCue 201+ (see picture above) only needs to be cleaned when an error code appears on the display (e.g. 901 or 902), or if the hemoglobin values obtained are higher or lower than anticipated.

- **Before cleaning the optronic unit, begin with steps 1-4 as outlined above for cleaning the HemoCue 201+ cuvette holder.**
- **Then continue with steps 5-7 below to clean the optronic unit.**



5. Push a HemoCue Cleaner, or a lint free cotton swab, moistened with alcohol (20-70% without additives) or water, inside the device as far as possible. Move it from side to side 5 to 10 times. DO NOT attempt to use an alcohol prep pad to clean inside the device.

6. Push and pull the HemoCue Cleaner or cotton swab in and out of the device opening (on the left side where the optronic unit is located).
7. Remove the HemoCue Cleaner or cotton swab from the device. If the HemoCue Cleaner or cotton swab is stained, repeat steps 5 and 6 to continue cleaning the optronic unit.
8. Wait 15 minutes before replacing the cuvette holder and using the HemoCue 201+.

HemoCue 201+ and HemoCue 301 Supply Ordering

Local agencies are responsible for procuring all related supplies for capillary sampling.

HemoCue 201+ and HemoCue 301 microcuvettes will be purchased by local agencies directly from HemoCue. Please place your order with:

Email: Alyssa Whitney
Phone: 720-836-9223

HemoCue 201+ Microcuvette Ordering Information
Part Number 111716 - Box of 200 (4 vials of 50 each) HemoCue 201+ Microcuvettes

For agencies that need smaller quantities:
Part Number 111715 – 100 individually wrapped HemoCue Microcuvettes

HemoCue 301 Microcuvette Ordering Information:

Part Number 11801 - Box of 200 (4 vials of 50 each) HemoCue 301+ Microcuvettes

HemoCue 201+ Troubleshooting

When the analyzer is turned on, it will perform a self-test to verify the performance of the optronic unit. If the self-test fails, or if experiencing any other issue, troubleshooting may be required to discover and resolve the problem.

For troubleshooting information regarding the HemoCue 201+, review the HemoCue 201+ Troubleshooting Guide (Appendix C).

If experiencing problems that are not able to resolved by taking the steps outlined in the troubleshooting guide, speak with your supervisor or call HemoCue Technical Support at 1-800-8811611.

HemoCue 201+ User Manual

For additional information regarding the HemoCue 201+, review the HemoCue 201+ User Manual.

HemoCue 301

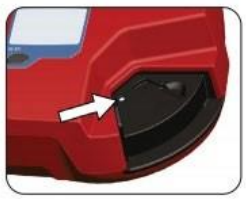
Hemoglobin Measurement

The HemoCue 301 hemoglobin analyzer operates in much the same way as the HemoCue 201+ hemoglobin analyzer. However, instead of measurements taking 40 to 240 seconds to display, once the filled microcuvette has been placed in the cuvette holder and rotated into the measuring position, the HemoCue 301 will display the measured hemoglobin value within 3 seconds.

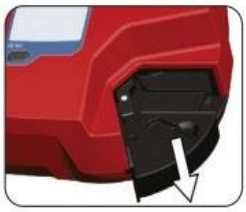
HemoCue 301 Cuvette Holder Cleaning

Clean cuvette holder after each day of use by following these steps:

1. Turn off the analyzer. While the cuvette holder is still in the loading position, press the catch using a pointed object

1 

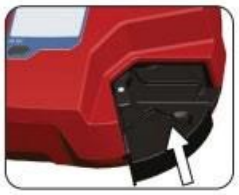
2. While still pressing the catch, carefully pull out the cuvette holder.

2 

3. Clean the cuvette holder with alcohol (20-70%) or mild detergent.

3 

4. Wait 15 minutes to air dry before replacing the cuvette holder (making sure that it's locked in place by the catch) and using the HemoCue 301.

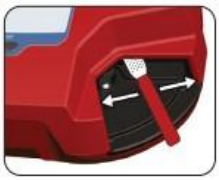
4 

HemoCue 301 Optical Parts Cleaning

The optronic unit inside the HemoCue 301 (see picture) only needs to be cleaned when an error code appears on the display (e.g. E00, E01, E02, E08, E10-30), or if the hemoglobin values obtained are higher or lower than anticipated.

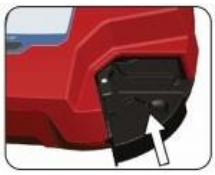
Before cleaning the optronic unit, first follow steps 1-2 as outlined above for cleaning the HemoCue 301 cuvette holder. Then continue with steps 3-6 below to clean the optronic unit.

1. Push a HemoCue Cleaner, or a lint free cotton swab, moistened with alcohol (20-70% without additives) or water, inside the device as far as possible. Move it from side to side 5 to 10 times. DO NOT attempt to use an alcohol prep pad to clean inside the device.



2. Push and pull the HemoCue Cleaner or cotton swab in and out of the device opening (of the left side where the optronic unit is located).

3. Remove the HemoCue Cleaner or cotton swab from the device. If the HemoCue Cleaner or cotton swab is stained, repeat steps 3 and 4.



4. Wait 15 minutes to air dry before replacing the cuvette holder (making sure that it's locked in place by the catch) and using the HemoCue 301.

HemoCue 201+ and HemoCue 301 Supply Ordering

HemoCue 201+ and HemoCue 301 microcuvettes will be purchased by local agencies directly from HemoCue. Please place your order with:

Email: Alyssa Whitney
Phone: 720-836-9223

HemoCue 201+ Microcuvette Ordering Information

- Part Number 111716 - Box of 200 (4 vials of 50 each) HemoCue 201+ Microcuvettes

For agencies that need smaller quantities:

- Part Number 111715 – 100 individually wrapped HemoCue Microcuvettes

HemoCue 301 Microcuvette Ordering Information:

- Part Number 11801 - Box of 200 (4 vials of 50 each) HemoCue 301+ Microcuvettes

HemoCue 301 Troubleshooting

When the analyzer is turned on, it will perform a self-test to verify the performance of the optronic unit. If the self-test fails, or if experiencing any other issued, troubleshooting may be required to discover and resolve the problem.

For troubleshooting information review the HemoCue Hb 301 HemoCue Troubleshooting Guide (Appendix D). If problems cannot be resolved by following steps in the troubleshooting guide, speak with your supervisor or call HemoCue Technical Support at 1-800-881-1611.

HemoCue 301 User Manual

For additional information regarding the HemoCue 301, review the HemoCue 301 User Manual.

McKesson Consult

The McKesson Consult hemoglobin analyzer is a portable instrument with a stationary cuvette holder and display screen.

- It can operate on AC power, but also contains a rechargeable battery that can last up to 40 days if fully charged.
- The battery can be charged via the USB port of a computer, or by connecting the USB cord to the AC adapter, and plugging the AC adapter into a power outlet.

McKesson Consult Operation

To obtain a reading, it is not necessary to turn the unit on (the device is always on and does not have an "on" or "off" button).

1. Place a filled microcuvette in the cuvette holder and press down gently until a "click" is felt. The hemoglobin measurement (expressed as grams per deciliter or g/dl) will appear on the display within a few seconds.
2. As soon as the hemoglobin value appears, immediately pull the microcuvette out of cuvette holder. After reading the sample, the value will remain displayed on the screen until the next measurement is taken.
3. To erase the latest result, press down on the empty cuvette holder until a "click" is felt.

McKesson Consult Cuvette Holder and Device Cleaning

Clean cuvette holder and device after each day of use by following these steps:

1. Pull the backside of the cuvette holder towards you and lift up.

2. Using a lint-free cotton swab, clean the cuvette holder with cold water or a mild detergent, followed by a disinfectant. Dry thoroughly.

3. Reinsert the dry cuvette holder by pressing down until you feel a “click”.

4. Clean the device with cold water or a mild detergent, followed by disinfectant. DO NOT spray the instrument when cleaning, as this will damage the instrument!

McKesson Consult Cuvette Holder and Device Cleaning

Clean cuvette holder and device after each day of use by following these steps:

1. Pull the backside of the cuvette holder towards you and lift up.

2. Using a lint-free cotton swab, clean the cuvette holder with cold water or a mild detergent, followed by a disinfectant. Dry thoroughly.

3. Reinsert the dry cuvette holder by pressing down until you feel a “click”.

4. Clean the device with cold water or a mild detergent, followed by disinfectant. DO NOT spray the instrument when cleaning, as this will damage the instrument!

McKesson Consult Troubleshooting

For McKesson Consult troubleshooting information, review the McKesson Consult Troubleshooting guide (Appendix E).

If experiencing problems that are not able to resolved by taking the steps outlined in the operating manual, speak with your supervisor or call McKesson technical support at (855) 625-4677.

McKesson Consult User Manual

For additional information regarding the McKesson Consult, review the McKesson Consult User Manual.

Chapter 4. How to Perform a Capillary Sampling Test

Participant Consent

Prior to any lab testing (including the completion of a hemoglobin blood test via capillary sampling), have the Authorized Representative read and sign the "Consent" signature type using the signature pad. The "Consent" signature type may be selected by using the "Signatures" button located at the bottom of the Medical Screen in HANDS.

Select Work Area

Select a work area to complete the capillary sampling test. An ideal work area:

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

Explain Procedure

Explain the procedure to the Authorized Representative in simple terms.

Example:
"I am going to make a little poke in your child's finger to get a few drops of blood to put into this little container. Then I am going to put it into this machine to find out how much hemoglobin it has in it."

Reassure them that you will make it as quick and painless as possible, but also be honest with participants if they ever ask if it may hurt. Answer by letting them know that it may hurt a little, but only for a moment.

Perform Hand Hygiene and Put on Gloves

Perform Hand Hygiene (either by washing hands or using an alcohol-based hand sanitizer) before putting on unused gloves.

Assemble Supplies
Assemble all necessary supplies in order to perform the capillary sampling test.

- Hemoglobin Analyzer
- Alcohol prep pads
- Sterile lancet
- Lint-free tissues/KimWipes® or Gauze pads
- Microcuvette (remove 1 at a time & reseal container)
- Bandages (not for children under age 2)
- Sharps container
- Biohazard bag
- 10% bleach solution or EPA-registered disinfectant

Daily Steps for Performing Hemoglobin Tests Continued Choose Site

The ring and middle fingers are the primary testing sites for all WIC participants for whom capillary sampling is indicated. Avoid using fingers with rings on them.

The heel may only be used for infants 9-11 months of age who have not yet began to learn to walk.

1. Position Participant

When performing a fingerstick, position the participant comfortably seated with their arm extended, (but lower than their heart), with their palm facing up.

When performing a heel stick, position the infant laying comfortably on their back.

2. Warm the Site (If Necessary)

The site should not be cold, blue, swollen or calloused.
If cold, warm the site by holding it in your hands, rubbing the site for a minute, or by have the Authorized Representative wash the site vigorously with warm running water and soap.

3. Cleanse the Site

- Cleanse the site thoroughly with an alcohol pad (unless the Authorized Representative already washed the site with warm water and soap).
- Wipe the site with a tissue or lint-free wipe. Be sure skin is dry.
- DO NOT touch the prepared site after cleaning.

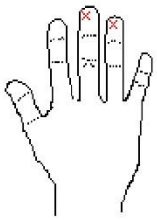
Note: Pooled alcohol at the puncture site will dilute and hemolyze the blood, giving a lower reading, if the skin surface is not dried completely.

4. Hold the Site

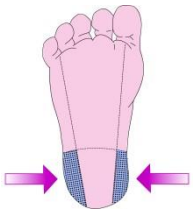
When performing a fingerstick, apply gentle pressure near the participants first finger joint.

When performing a heel stick, grasp the heel between your thumb and forefinger with your other fingers underneath the infant's calf. Apply a small amount of pressure to flex the foot back.

5. Puncture



If performing a fingerstick, puncture off the centerline of the participant's fingertip using a lancet. (See figure above.)



If performing a heel stick, puncture only on the medial or lateral side of the bottom surface of the heel using a lancet. (See figure to the left.)

Note: 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 microcuvette.

6. Fill the Microcuvette

To ensure accuracy, 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 squeezing or milking the site to force blood to emerge as this can dilute the blood and gives a false low reading.

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 microcuvette tip.

Touch the tip of the microcuvette, pointing downward, into the middle of the blood drop so the microcuvette touches the skin. Allow the microcuvette to fill in one step. The microcuvette will fill itself automatically. Never "top off" the microcuvette if it doesn't fill in the first attempt.

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

7. Prepare the Cuvette for Testing

Wipe off the flat outside surfaces of the microcuvette using gauze or a lint-free wipe. Avoid wiping the open slit of the microcuvette.

8. Measuring Hemoglobin Value

Measure the hemoglobin value in the microcuvette by following the manufacturer's directions for the hemoglobin analyzer used in your local agency's clinic (See Chapter 3). Immediately record the value obtained, so that it can be entered into the HANDS medical screen.

9. 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.

10. Cleanse Surface

If any blood spills on the hemoglobin analyzer, work surfaces, or your skin, clean with a 10% bleach solution or disinfectant spray immediately.

11. 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.
- Sharps container: Throw away all lancets and used microcuvettes in the sharps container.

12. Remove Gloves and Perform Hand Hygiene

- Remove and discard gloves after disposing the other supplies.
- If your gloves are contaminated with blood, place them in the biohazard bag with the other supplies.
- Perform hand hygiene after removing your gloves.

13. Perform Another Capillary Sampling Test (If Necessary)

If performing another capillary sampling test, begin by putting on a new pair of gloves, and assembling new supplies needed for another test.

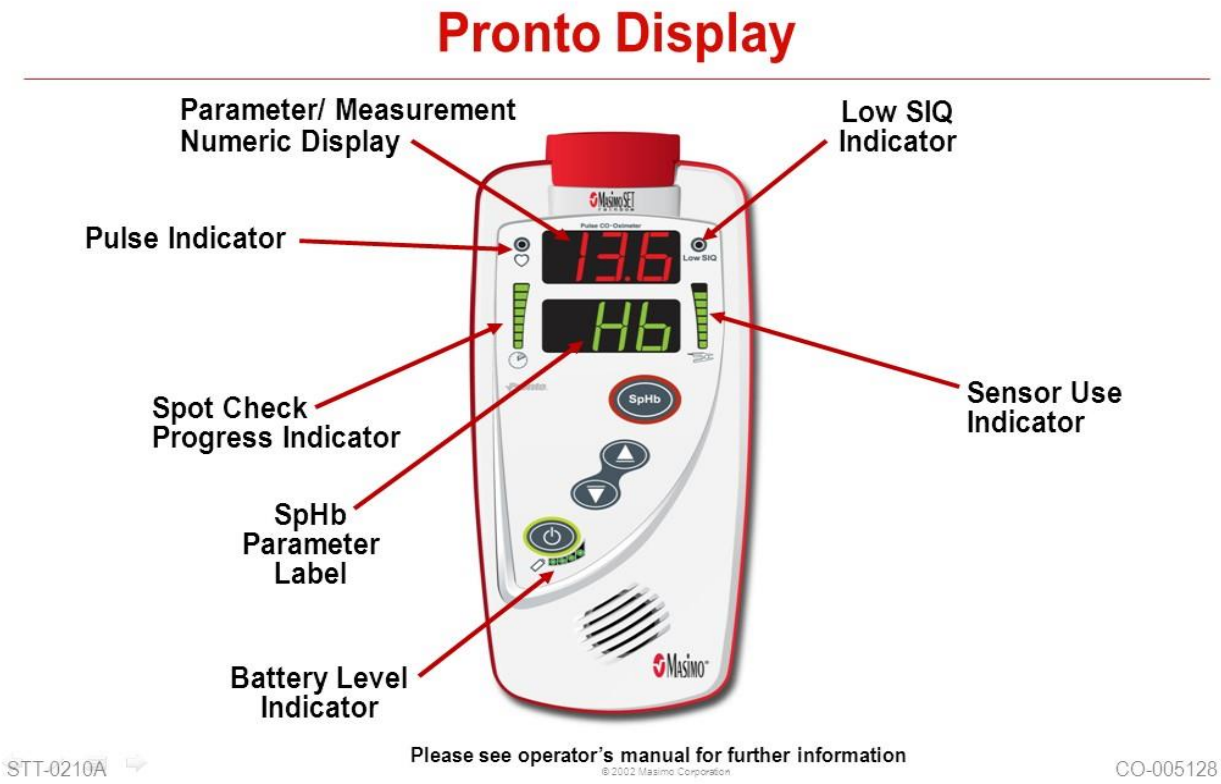
14. Remove Gloves and Perform Hand Hygiene

Repeat the steps of performing hand hygiene after each capillary sampling test.

Chapter 5. Masimo Pronto Equipment

Masimo Pronto Pulse CO-Oximeter

The Masimo Pronto measures total hemoglobin concentration of the blood via a sensor attached to the machine that emits multiple light waves 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.



Parameter/Measurement Numeric Display

Displays parameter/measurement numeric hemoglobin values once a spot check test is complete.

Pulse Indicator

Flashes with patient's pulse reading (BPM) during spot check test period

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.

SpHb Parameter Label

Displays parameter/measurement label data once a spot check test is complete.

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

The Low SIQ Indicator illuminates when the signal is too low to complete the test, indicating that it will be necessary to restart the test.

Sensor Use Indicator

The Sensor Use Indicator 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.

Power On/Off

Powers the instrument on or off. Press the button once to power on, press and hold the Button for 2 seconds to power off.

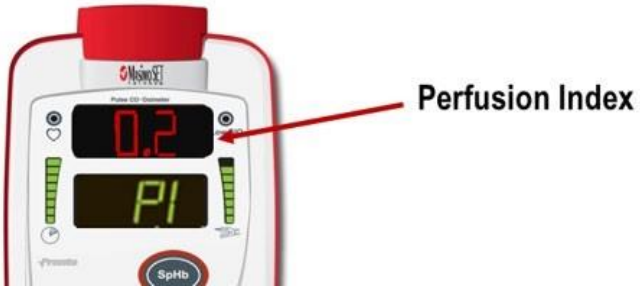
SpHb Button

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 and Down Buttons

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.

Perfusion Index (PI)



Perfusion Index (PI) is a numeric indication of the pulse strength at the measurement site. The PI numerical value on the Masimo Pronto ranges between 0.02% and 20%. To successfully conduct a test the "PI" perfusion index must measure 1.0 or greater.

- PI varies between monitoring sites and from patient to patient, as physiologic conditions vary
- Lower values indicate lower perfusion meaning decreased blood flow
- Several possible causes (e.g. cold hands, Vasoconstriction (narrowing of the blood vessels), Hypovolemia (decreased blood volume), Peripheral Vascular Disease, etc.)
- 4-6% of the population have subclinical issues that will prevent a good reading (carboxyhemoglobin, other irregularities)
- Monitor the trend of the PI for changes in physiologic conditions

Battery Compartment

- Battery Compartment located in back panel
- Holds 4 "AA" alkaline or rechargeable batteries
- Operates up to 8 hours (usually 200-250 tests per battery replacement)

- The Pronto cannot be plugged in, it only uses battery power

Disabling Pulse Rate and Oxygen Saturation (Optional)

Pulse rate and oxygen saturation are features of the Masimo Pronto that are not utilized by the WIC program. Disabling these features is optional, but will help to prolong battery life. To disable them take the following steps.

1. Press Up and Down arrow buttons simultaneously for 5 seconds
2. Press the Sp/Hb button repeatedly until "O2" (Oxygen Saturation) appears on the display.
3. Press either the up or down arrow to turn "off" oxygen saturation
4. Press SpHb to confirm your choice
5. "Pr" (Pulse Rate) will appear next in the display
6. Press either the up or down arrow to turn "off" pulse rate.
7. Press SpHb to confirm your choice

Patient Cable

One-foot patient cable that connects to rainbow DCI and rainbow DCIP digit sensors. To connect the Patient Cable, plug the red end of the cable into the port on top of the Masimo Pronto.

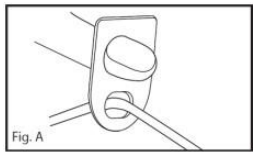
Rainbow DCI Digit Sensor

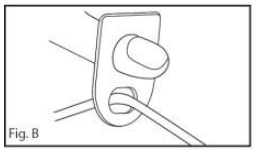
Adult-sized sensor that can be connected to the RC1 Patient Cable when performing tests on adults. Includes a slender digit gauge (see slender digit gauge description below).

Rainbow DCIP Digit Sensor

Pediatric-sized sensor that can be connected to the RC1 Patient Cable when performing tests on children or women with slender fingers. The finger of a child must be long enough and wide enough reach the end of the sensor. If the child's finger isn't long enough, the hemoglobin value will need to be obtained via a capillary sampling test.

Slender Digit Gauge





Aids in selecting the appropriate sensor (Adult or Pediatric) and digit before completing a test.

Cleaning the Masimo 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 the Rainbow Cables

- 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.

Ordering, Returning, and Replacing Masimo Equipment

To order new Masimo Pronto machines or replacement sensors contact Diane Himmelberger - Masimo representative. To return or replace Masimo machines, contact your Local Agency's Nutrition 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.

Masimo Pronto Troubleshooting

For Masimo Pronto troubleshooting, review the Masimo Pronto Troubleshooting guide (Appendix F).

If experiencing problems that are not able to resolved by taking the steps outlined in the troubleshooting guide, speak with your supervisor or call Masimo technical support at 1-800-326-4890.

Masimo Pronto User Manual

For all other information regarding the Masimo Pronto, Review the Masimo Pronto User Manual.

Chapter 6. How to Perform a Test Using the Masimo Pronto

Participant Consent

Prior to any hematology testing (including the completion of a hemoglobin blood test using the Masimo Pronto), have the Authorized Representative read and sign the "Consent" signature type using the signature pad. (The "Consent" signature type may be selected by using the "Signatures" button located at the bottom of the Medical Screen in HANDS.)

Choose a Location

The selected location for using the Pronto device should be a comfortable area, free of excessive noise or distractions, such as a private office space. It is not recommended to conduct hemoglobin tests with the Pronto device in a common lab area where other measurements or capillary sampling tests are being completed. The sights and sounds of other participants who may be stressed or upset by lab procedures may make it more difficult to keep participants relaxed and motionless while using the Pronto.

Explain Procedure

Explain the procedure to the Authorized Representative in simple terms.

Example:
"I am going to place a sensor on your child's finger to find out how much hemoglobin is in his/her blood. Your child will need to sit completely still for a couple of minutes in order to complete the test, but don't worry, it's completely painless."

Perform Hand Hygiene

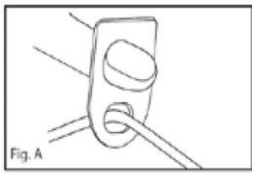
Perform Hand Hygiene (either by washing hands or using an alcohol-based hand sanitizer).

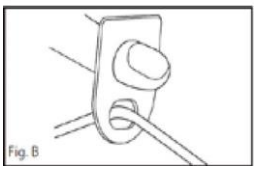
Position Participant

Position the participant comfortably seated with their arm extended, (but lower than their heart), with their palm facing down.

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 (below).

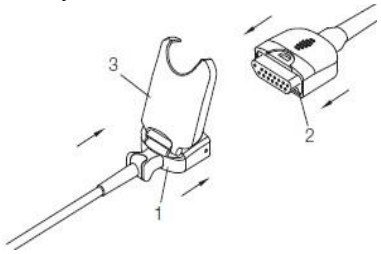




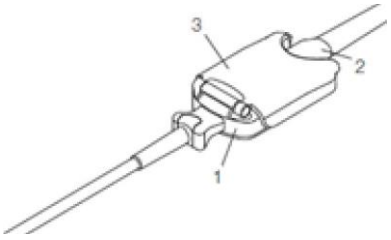
- If the gauge circle stops at any point of the nail bed before the cuticle, the sensor can be used on that digit.
- If the gauge slides past the cuticle as shown in Figure B, the digit is too slender for this sensor. Select a different digit or use a pediatric / slender digit sensor on the patient (see instructions below for disconnecting and connecting sensors).
- Remove the gauge from the digit before sensor application.

Disconnect and Connect Sensor

(If necessary)



- To disconnect the sensor, lift the protective cover (above, labeled 3) to gain access to the sensor connector (labeled 1).



- Pull firmly on the sensor connector to remove from the patient cable (labeled 2). To avoid damage, pull on the sensor connector, not the cable.
- To connect the sensor, properly orient the sensor connector and insert the sensor connector completely into the patient cable connector.
- Completely close the protective cover.

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.
- Select the participants testing finger in the following priority:
    - Ring or middle finger

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

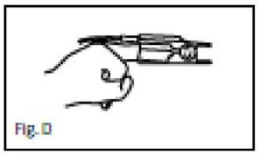
Note: DO NOT use pinky or index fingers. DO NOT use anatomically abnormal fingers (e.g. clubbed, deviated, etc.).

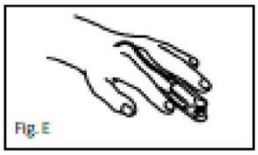
You can use the Pronto on sites with nail polish and/or acrylic nails. Some types of nail polish may interfere with the test and prevent a reading, but it is advised to attempt tests with nail polish. If the Pronto displays a result from a site with nail polish, the result is within the specifications for accuracy required by FDA. If a reading fails, it does not reduce the number of tests left on the sensor.

Cleanse the Site

Cleanse the site thoroughly with an alcohol pad.

Sensor Placement





- Place the participant's selected finger inside of the sensor.
- 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).
- 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.

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.

Light Shielding

Cover the sensor with a hand (either your hand or a caregivers) or cloth to shield the sensor from excessive light. Excessive light may increase the time needed to complete tests and cause tests to fail more often.

Starting a Hemoglobin Test using the Masimo Pronto

Press the power button to activate the Pronto.

a. The Pronto will run a Self-Test.
b. The Pronto will display the number of sensor tests remaining on the sensor. (New sensors will only function for a specific number of tests (200, 400, or 1000).
c. When the Pronto reads SEN OFF it is ready for testing.
d. Scrolling zeros appear to indicate sensor initialization.
e. Dashes appear to indicate testing has begun.
f. 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.
g. Pulse indicator light will flash with each heartbeat.
h. It will take 1 to 3 minutes for the Pronto to acquire and display a hemoglobin measurement.
i. The Spot Check Progress indicator incrementally illuminates from bottom to top and an audible tone will sound when the hemoglobin measurement is ready to display.

Display Hemoglobin Test Result

Press SpHb button when ready to view hemoglobin results (hemoglobin data will available for 5 minutes after the test has completed by depressing either the up or down arrow).

Record Hemoglobin Test Result

Immediately record the value obtained, so that it can be entered into the HANDS medical screen.

Remove Sensor

Remove the sensor from the participant's finger.

Turn off Masimo Pronto

Turn off the Masimo Pronto by holding down the Power Button for 2 seconds. (It will also turn off automatically if not used for more than 1 minute.

Chapter 7: Hemoglobin Value Results

Different Hemoglobin Values

The CDC has established hemoglobin cutoff values below which someone is considered at risk for anemia (see Appendix A). Hemoglobin cut-off values vary, depending upon participant smoking status, level of elevation, and category. There are 6 different tables based on elevation level. From there, each table is broken down by smoking status, and category (pregnant [by trimester], postpartum/breastfeeding, and children and infants). One of these tables should be posted in your lab for you to evaluate your participant's test result.

After obtaining hemoglobin values (via the Masimo Pronto or capillary sampling) and entering them into the HANDS system, there are four possible courses of action depending on the risk assigned, and the hemoglobin value obtained. Each of these four courses of action will be reviewed in this chapter.

Normal Hemoglobin Value

If the hemoglobin value obtained is above the "Low Hemoglobin" range based on the CDC cutoff values for hemoglobin (Appendix A), the participant's hemoglobin is considered normal, so no risk code will be generated when the value is entered into HANDS, and no further action is necessary.

"Low Hemoglobin" Value

If the hemoglobin value obtained is within the "Low Hemoglobin" range based on the CDC cutoff values for hemoglobin (Appendix A), risk code 201.2 will be generated when the value is entered into HANDS. No additional referral is required since it is a low risk code. However, a referral to a healthcare provider may be provided to determine the cause of the low hemoglobin and to discuss possible treatment options. Since iron deficiency anemia is by far the most common cause of low hemoglobin values, it may also be useful to attempt to determine the potential cause and possibly discuss tips to increase dietary iron intake.

"Nutritionist" Hemoglobin Value

If the hemoglobin value obtained is within the "Nutritionist" range based on the CDC cutoff values for hemoglobin (Appendix A), risk code 201.1 will be generated when the value is entered into HANDS. When this occurs, have a second hemoglobin test completed (preferably by another staff member), using a finger on the participant's other hand. The higher of the two hemoglobin values shall be entered into the HANDS computer system.

It's required to refer participants assigned risk code 201.1 to a medium risk nutritionist or high-risk nutritionist since it is a medium risk code. A referral to a healthcare provider may be provided to determine the cause of the low hemoglobin and to discuss possible treatment options. Since iron deficiency anemia is by far the most common cause of low hemoglobin values, it may also be useful to attempt to determine the potential cause and possibly discuss tips to increase dietary iron intake.

"Very Low Hemoglobin" Value

A very low hemoglobin value (see Appendix B) is a serious medical concern and is life-threatening. If a very low hemoglobin value is obtained, have a second hemoglobin test completed (preferably by another staff member), using a finger on the participant's other hand. The higher of the two hemoglobin values shall be entered into the HANDS computer system.

Local Agencies shall also establish a referral plan (in conjunction with county/agency Health Program Officers), 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 at an emergency medical center. All referrals shall be documented in HANDS. An optional referral form is available on the WIC Manuals, Supplemental Materials section of azwic.gov.

It's also required to refer participants with very low hemoglobin values to a medium risk nutritionist or high-risk nutritionist since it is a medium risk code (201.1).

Table of Very Low Hemoglobin Values

Altitude	Hemoglobin Reading (←g/dL)
0-2,999 (sea level)	6.5
3000-3999	6.7
4000-4999	6.8
5000-5999	7.0
6000-6999	7.2
7000-7999	7.5
8000-8999	7.8
9000-9999	7.8
10,000 – 11,000	7.9

Cigarette Smoking – add to cut off value	Change in Hemoglobin Reading (←g/dL)
0.5 - ← 1.0 pack per day	+0.3
1.0 - ←2.0 packs per day	+0.5
↗ 2.0 packs per day	+0.7
All smokers	+0.3

Appendix A – CDC Cutoffs for Anemia

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

			Pregnant	Pregnant	Pregnant	Breastfeeding/ Postpartum	Breastfeeding/ Postpartum	Infant/Child	Child
Smoking Status	WIC Code	Risk Level	1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	201.2	Low-Risk	8.6 to 10.9	8.2 to 10.4	8.6 to 10.9	9.3 to 11.7	8.9 to 11.9	8.0 to 10.9	8.3 to 11.0
Non-Smoker	201.1 (Nutritionist)	Medium-Risk	6.6 to 8.5	6.6 to 8.1	6.6 to 8.5	6.6 to 9.2	6.6 to 8.8	6.6 to 7.9	6.6 to 8.2
Non-Smoker	201.1* (Very Low Hgb)	Medium-Risk	6.5 or lower	6.5 or lower	6.5 or lower	6.5 or lower	6.5 or lower	6.5 or lower	6.5 or lower
10-19 cigarettes/d	201.2	Low-Risk	8.9 to 11.2	8.4 to 10.7	8.9 to 11.2	9.6 to 12.0	9.5 to 12.2		
10-19 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	6.9 to 8.8	6.9 to 8.3	6.9 to 8.8	6.9 to 9.5	6.9 to 9.4		
10-19 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	6.8 or lower	6.8 or lower	6.8 or lower	6.8 or lower	6.8 or lower		
20-39 cigarettes/d	201.2	Low-Risk	9.6 to 11.4	8.0 to 10.9	9.6 to 11.4	9.8 to 12.2	10.0 to 12.4		
20-39 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.1 to 9.5	7.1 to 7.9	7.1 to 9.5	7.1 to 9.7	7.1 to 9.9		
20-39 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower		
40+ cigarettes/d	201.2	Low-Risk	10.3 to 11.6	7.6 to 11.1	10.3 to 11.6	10.0 to 12.4	10.5 to 12.6		
40+ cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.3 to 10.2	7.3 to 7.5	7.3 to 10.2	7.3 to 9.9	7.3 to 10.4		
40+ cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower		

*Healthcare Referral Required

Blood Lead Levels Cutoffs for Lead Poisoning (Assign WIC Code 211)

WIC Category	Blood Lead Level Cutoff
Children	3.5 micrograms per deciliter or higher
Infants, Pregnant, BF, Postpartum	5.0 micrograms per deciliter or higher

Revised: October 2024

Cutoff values for Hemoglobin Levels at 3000-3,999 feet

			Pregnant	Pregnant	Pregnant	Breastfeeding/ Postpartum	Breastfeeding/ Postpartum	Infant/Child	Child
Smoking Status	WIC Code	Risk Level	1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	201.2	Low-Risk	9.1 to 11.1	8.7 to 10.6	9.1 to 11.1	9.5 to 11.9	9.4 to 12.1	8.4 to 11.1	8.8 to 11.2
Non-Smoker	201.1 (Nutritionist)	Medium-Risk	6.8 to 9.0	6.8 to 8.6	6.8 to 9.0	6.8 to 9.4	6.8 to 9.3	6.8 to 8.3	6.8 to 8.7
Non-Smoker	201.1* (Very Low Hgb)	Medium-Risk	6.7 or lower	6.7 or lower	6.7 or lower	6.7 or lower	6.7 or lower	6.7 or lower	6.7 or lower
10-19 cigarettes/d	201.2	Low-Risk	9.4 to 11.4	8.9 to 10.9	9.4 to 11.4	9.8 to 12.2	9.9 to 12.4		
10-19 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.1 to 9.3	7.1 to 8.8	7.1 to 9.3	7.1 to 9.7	7.1 to 9.8		
10-19 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower		
20-39 cigarettes/d	201.2	Low-Risk	10.1 to 11.6	8.5 to 11.1	10.1 to 11.6	10.0 to 12.4	10.4 to 12.6		
20-39 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.3 to 10.0	7.3 to 8.4	7.3 to 10.0	7.3 to 9.9	7.3 to 10.3		
20-39 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower		
40+ cigarettes/d	201.2	Low-Risk	10.8 to 11.8	8.1 to 11.3	10.8 to 11.8	10.2 to 12.6	10.9 to 12.8		
40+ cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.5 to 10.7	7.5 to 8.0	7.5 to 10.7	7.5 to 10.1	7.5 to 10.8		
40+ cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.4 or lower	7.4 or lower	7.4 or lower	7.4 or lower	7.4 or lower		

*Healthcare Referral Required

Blood Lead Levels Cutoffs for Lead Poisoning (Assign WIC Code 211)

WIC Category	Blood Lead Level Cutoff
Children	3.5 micrograms per deciliter or higher
Infants, Pregnant, BF, Postpartum	5.0 micrograms per deciliter or higher

Revised: October 2024

Cutoff values for Hemoglobin Levels at 4000-4,999 feet

			Pregnant	Pregnant	Pregnant	Breastfeeding/ Postpartum	Breastfeeding/ Postpartum	Infant/Child	Child
Smoking Status	WIC Code	Risk Level	1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	201.2	Low-Risk	9.2 to 11.2	8.9 to 10.7	9.2 to 11.2	9.6 to 12.0	9.5 to 12.2	8.5 to 11.2	8.9 to 11.3
Non-Smoker	201.1 (Nutritionist)	Medium-Risk	6.9 to 9.1	6.9 to 8.8	6.9 to 9.1	6.9 to 9.5	6.9 to 9.4	6.9 to 8.4	6.9 to 8.8
Non-Smoker	201.1* (Very Low Hgb)	Medium-Risk	6.8 or lower	6.8 or lower	6.8 or lower	6.8 or lower	6.8 or lower	6.8 or lower	6.8 or lower
10-19 cigarettes/d	201.2	Low-Risk	9.5 to 11.5	9.1 to 11.0	9.5 to 11.5	9.9 to 12.3	10.0 to 12.5		
10-19 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.2 to 9.4	7.2 to 9.0	7.2 to 9.4	7.2 to 9.8	7.2 to 9.9		
10-19 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.1 or lower	7.1 or lower	7.1 or lower	7.1 or lower	7.1 or lower		
20-39 cigarettes/d	201.2	Low-Risk	10.3 to 11.7	8.7 to 11.2	10.3 to 11.7	10.1 to 12.5	10.5 to 12.7		
20-39 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.4 to 10.2	7.4 to 8.6	7.4 to 10.2	7.4 to 10.0	7.4 to 10.4		
20-39 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.3 or lower	7.3 or lower	7.3 or lower	7.3 or lower	7.3 or lower		
40+ cigarettes/d	201.2	Low-Risk	11.0 to 11.9	8.3 to 11.4	11.0 to 11.9	10.3 to 12.7	11.0 to 12.9		
40+ cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.6 to 10.9	7.6 to 8.2	7.6 to 10.9	7.6 to 10.2	7.6 to 10.9		
40+ cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower		

*Healthcare Referral Required

Blood Lead Levels Cutoffs for Lead Poisoning (Assign WIC Code 211)

WIC Category	Blood Lead Level Cutoff
Children	3.5 micrograms per deciliter or higher
Infants, Pregnant, BF, Postpartum	5.0 micrograms per deciliter or higher

Revised: October 2024

Cutoff values for Hemoglobin Levels at 5000-5,999 feet

			Pregnant	Pregnant	Pregnant	Breastfeeding/ Postpartum	Breastfeeding/ Postpartum	Infant/Child	Child
Smoking Status	WIC Code	Risk Level	1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	201.2	Low-Risk	9.4 to 11.4	9.0 to 10.9	9.4 to 11.4	9.8 to 12.2	9.6 to 12.4	8.6 to 11.4	9.0 to 11.5
Non-Smoker	201.1 (Nutritionist)	Medium-Risk	7.1 to 9.3	7.1 to 8.9	7.1 to 9.3	7.1 to 9.7	7.1 to 9.5	7.1 to 8.5	7.1 to 8.9
Non-Smoker	201.1* (Very Low Hgb)	Medium-Risk	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower	7.0 or lower
10-19 cigarettes/d	201.2	Low-Risk	9.7 to 11.7	9.3 to 11.2	9.7 to 11.7	10.1 to 12.5	10.2 to 12.7		
10-19 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.4 to 9.6	7.4 to 9.2	7.4 to 9.6	7.4 to 10.0	7.4 to 10.1		
10-19 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.3 or lower	7.3 or lower	7.3 or lower	7.3 or lower	7.3 or lower		
20-39 cigarettes/d	201.2	Low-Risk	9.7 to 11.7	9.3 to 11.2	9.7 to 11.7	10.1 to 12.5	10.2 to 12.7		
20-39 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.6 to 9.6	7.6 to 9.2	7.6 to 9.6	7.6 to 10.0	7.6 to 10.1		
20-39 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower		
40+ cigarettes/d	201.2	Low-Risk	11.1 to 12.1	8.5 to 11.6	11.1 to 12.1	10.5 to 12.9	11.2 to 13.1		
40+ cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.8 to 11.0	7.8 to 8.4	7.8 to 11.0	7.8 to 10.4	7.8 to 11.1		
40+ cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.7 or lower	7.7 or lower	7.7 or lower	7.7 or lower	7.7 or lower		

*Healthcare Referral Required

Blood Lead Levels Cutoffs for Lead Poisoning (Assign WIC Code 211)

WIC Category	Blood Lead Level Cutoff
Children	3.5 micrograms per deciliter or higher
Infants, Pregnant, BF, Postpartum	5.0 micrograms per deciliter or higher

Cutoff values for Hemoglobin Levels at 6000-6,999 feet

			Pregnant	Pregnant	Pregnant	Breastfeeding/ Postpartum	Breastfeeding/ Postpartum	Infant/Child	Child
Smoking Status	WIC Code	Risk Level	1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	201.2	Low-Risk	9.5 to 11.6	9.2 to 11.1	9.5 to 11.6	10.0 to 12.4	9.8 to 12.6	8.8 to 11.6	9.2 to 11.7
Non-Smoker	201.1 (Nutritionist)	Medium-Risk	7.3 to 9.4	7.3 to 9.1	7.3 to 9.4	7.3 to 9.9	7.3 to 9.7	7.3 to 8.7	7.3 to 9.1
Non-Smoker	201.1* (Very Low Hgb)	Medium-Risk	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower	7.2 or lower
10-19 cigarettes/d	201.2	Low-Risk	9.8 to 11.9	9.4 to 11.4	9.8 to 11.9	10.3 to 12.7	10.3 to 12.9		
10-19 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.6 to 9.7	7.6 to 9.3	7.6 to 9.7	7.6 to 10.2	7.6 to 10.2		
10-19 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower		
20-39 cigarettes/d	201.2	Low-Risk	10.6 to 12.1	9.0 to 11.6	10.6 to 12.1	10.5 to 12.9	10.8 to 13.1		
20-39 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.8 to 10.5	7.8 to 8.9	7.8 to 10.5	7.8 to 10.4 to	7.8 to 10.7		
20-39 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.7 or lower	7.7 or lower	7.7 or lower	7.7 or lower	7.7 or lower		
40+ cigarettes/d	201.2	Low-Risk	11.3 to 12.3	8.6 to 11.8	11.3 to 12.3	10.7 to 13.1	11.3 to 13.3		
40+ cigarettes/d	201.1 (Nutritionist)	Medium-Risk	8.0 to 11.2	8.0 to 8.5	8.0 to 11.2	8.0 to 10.6	8.0 to 11.2		
40+ cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.9 or lower	7.9 or lower	7.9 or lower	7.9 or lower	7.9 or lower		

*Healthcare Referral Required

Blood Lead Levels Cutoffs for Lead Poisoning (Assign WIC Code 211)

WIC Category	Blood Lead Level Cutoff
Children	3.5 micrograms per deciliter or higher
Infants, Pregnant, BF, Postpartum	5.0 micrograms per deciliter or higher

Cutoff values for Hemoglobin Levels at 7000-7,999 feet

			Pregnant	Pregnant	Pregnant	Breastfeeding/ Postpartum	Breastfeeding/ Postpartum	Infant/Child	Child
Smoking Status	WIC Code	Risk Level	1st Trimester 0 – 13 weeks	2nd Trimester 14 – 26 weeks	3rd Trimester 27 + weeks	12 years to 14 years 11 months	15 years +	Infant 6 to 23 months	Child 2 to 5 years
Non-Smoker	201.2	Low-Risk	9.7 to 11.9	9.4 to 11.4	9.7 to 11.9	10.3 to 12.7	9.9 to 12.9	8.9 to 11.9	9.3 to 12.0
Non-Smoker	201.1 (Nutritionist)	Medium-Risk	7.6 to 9.6	7.6 to 9.3	7.6 to 9.6	7.6 to 10.2	7.6 to 9.8	7.6 to 8.8	7.6 to 9.2
Non-Smoker	201.1* (Very Low Hgb)	Medium-Risk	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower	7.5 or lower
10-19 cigarettes/d	201.2	Low-Risk	10.0 to 12.2	9.6 to 11.7	10.0 to 12.2	10.6 to 13.0	10.5 to 13.2		
10-19 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	7.9 to 9.9	7.9 to 9.5	7.9 to 9.9	7.9 to 10.5	7.9 to 10.4		
10-19 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	7.8 or lower	7.8 or lower	7.8 or lower	7.8 or lower	7.8 or lower		
20-39 cigarettes/d	201.2	Low-Risk	10.7 to 12.4	9.2 to 11.9	10.7 to 12.4	10.8 to 13.2	10.9 to 13.4		
20-39 cigarettes/d	201.1 (Nutritionist)	Medium-Risk	8.1 to 10.6	8.1 to 9.1	8.1 to 10.6	8.1 to 10.7	8.1 to 10.8		
20-39 cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	8.0 or lower	8.0 or lower	8.0 or lower	8.0 or lower	8.0 or lower		
40+ cigarettes/d	201.2	Low-Risk	11.4 to 12.6	8.8 to 12.1	11.4 to 12.6	11.0 to 13.4	11.4 to 13.6		
40+ cigarettes/d	201.1 (Nutritionist)	Medium-Risk	8.3 to 11.3	8.3 to 8.7	8.3 to 11.3	8.3 to 10.9	8.3 to 11.3		
40+ cigarettes/d	201.1* (Very Low Hgb)	Medium-Risk	8.2 or lower	8.2 or lower	8.2 or lower	8.2 or lower	8.2 or lower		

*Healthcare Referral Required

Blood Lead Levels Cutoffs for Lead Poisoning (Assign WIC Code 211)

WIC Category	Blood Lead Level Cutoff
Children	3.5 micrograms per deciliter or higher
Infants, Pregnant, BF, Postpartum	5.0 micrograms per deciliter or higher

Appendix B – Table of Very Low Hemoglobin Values

Table of Very Low Hemoglobin Values

Altitude	Hemoglobin Reading (←g/dL)
0-2,999 (sea level)	6.5
3000-3999	6.7
4000-4999	6.8
5000-5999	7.0
6000-6999	7.2
7000-7999	7.5
8000-8999	7.8
9000-9999	7.8
10,000 – 11,000	7.9

Cigarette Smoking – add to cut off value	Change in Hemoglobin Reading (←g/dL)
0.5 - ← 1.0 pack per day	+0.3
1.0 - ←2.0 packs per day	+0.5
↗ 2.0 packs per day	+0.7
All smokers	+0.3

Blood Lead Levels Cutoffs for Lead Poisoning (Assign WIC Code 211)

WIC Category	Blood Lead Level Cutoff
Children	3.5 micrograms per deciliter or higher
Infants, Pregnant, BF, Postpartum	5.0 micrograms per deciliter or higher

Appendix C – HemoCue 201 Troubleshooting Guide

US Troubleshooting Guide

If you are unable to resolve the problem by following this Troubleshooting Guide, please call your HemoCue distributor or HemoCue America.
LED = Light Emitting Diode. Note! Do not open the cover of the analyzer. The warranty is voided if the analyzer has been opened.

Symptom	Explanation	Action
The analyzer shows "ERROR" and a digit code 900–930.	May be an occasional fault.	Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, see specific error code below.
900	No stable endpoint found within the time range. 1. The microcuvette is faulty. 2. The circuit board is out of order.	1a. Check expiration date for the microcuvettes. 1b. Take a new microcuvette and repeat the measurement. 2. The analyzer needs service. Call your distributor.
901	Light intensity for the compensating LED is too low. 1. The optronic unit is dirty. 2. The optronic unit is out of order.	1. Clean the optronic unit, as described in the Maintenance section. 2. The analyzer needs service. Call your distributor.
902	Light intensity for the measuring LED is too low. 1. The optronic unit is dirty. 2. The optronic unit is out of order.	1. Clean the optronic unit, as described in the Maintenance section. 2. The analyzer needs service. Call your distributor.
903	1. The optronic unit is out of order.	1. The analyzer needs service. Call your distributor.
905	1. Light intensity for one of the LED´s is too high.	1. The analyzer needs service. Call your distributor.
906	1. Unstable blank value. The analyzer might be cold.	1. Turn off the analyzer and allow it to reach room temperature. If the problem continues, the analyzer needs service. Call your distributor.
907	1. The battery power is too low.	1a. The batteries need to be replaced. Turn off the analyzer and replace the batteries, 4 type AA. 1b. Use the power adapter.
908	The absorbance is too high. 1. Light blocking item in the cuvette holder.	1a. Check that the analyzer and microcuvettes are used according to the HemoCue Glucose 201 operating manual and instruction for use. 1b. The analyzer needs service. Call your distributor.
910	Seen during all phases of use, and is a fatal error. A read or write operation to the EEPROM did not succeed. 1. The EEPROM memory is out of order.	1a. Turn off the analyzer and turn it on again after 30 seconds and retry testing. 1b. The analyzer needs service. Call your distributor.
911	Seen during start up and is a fatal error. 1. The analyzer cannot detect a valid EEPROM memory configuration.	1a. Turn off the analyzer and turn it on again after 30 seconds and retry testing. 1b. The analyzer needs service. Call your distributor.
913	Seen during start up and is a fatal error. Self test of RAM memory failed. 1. The electronics are out of order.	1. The analyzer needs service. Call your distributor.
925	Seen at start up and is a fatal error. Calibration checksum is not valid. 1. The analyzer needs calibration.	1. The analyzer needs service. Call your distributor.
929	1. Communication error during internal hardware test.	1. The analyzer needs service. Call your distributor.
930	1. The electronic "SELFTEST" failed.	1a. Turn off the analyzer and allow it to reach room temperature. 1b. If the problem continues, the analyzer needs service. Call your distributor.
HHH	1. Measured value exceeds 444 mg/dL (24.6 mmol/L).	1. Check the expiration date of the microcuvettes. 2. Remeasure sample with fresh microcuvette.
No characters on the display.	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.	1a. Check that the power adapter is connected to the power source. 1b. Check that the power adapter is securely connected to the analyzer. 1c. Check that the adapter wire is not damaged. 2. Turn off the analyzer and replace the batteries, 4 type AA. 3. The analyzer needs service. Call your distributor.
The display gives erroneous characters.	1. The display is out of order. 2. The microprocessor is out of order.	1. The analyzer needs service. Call your distributor. 2. The analyzer needs service. Call your distributor.

Symptom	Explanation	Action
The display shows "▭"	1. The batteries need to be replaced. 2. If using power adapter, the adapter or circuit board is out of order.	1. Turn the analyzer off and replace the batteries, 4 type AA. 2a. Check that the power adaptor is properly connected and working. 2b. The analyzer needs service. Call your distributor.
The display does not switch from "SELFTEST" to "READY" or from "READY" to "⌛" (measuring).	1. The magnet in the cuvette holder may be missing. 2. The magnetic sensor is out of order.	1. The analyzer needs service. Call your distributor. 2. The analyzer needs service. Call your distributor.
Measurements on control materials out of range – either too HIGH or too LOW.	1. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 2. The optical eye of the microcuvette is contaminated. 3. The control has not been mixed well and/or is not at room temperature. 4. Air bubbles are present in the microcuvette. 5. The optronic unit is dirty. 6. The control is not suitable for use with the HemoCue Glucose 201 system. 7. The calibration of the analyzer has been changed. 8. The controls are beyond their expiration dates or have been improperly stored.	1. Check the expiration date and the storage conditions of the microcuvettes. 2. Remeasure the sample with a new microcuvette. 3. Make sure that the control is mixed well and at room temperature. 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. Only use controls intended for the HemoCue Glucose 201 system recommended by HemoCue. 7. The analyzer needs service. Call your distributor. 8. Check the expiration date and the storage conditions of the control. Take a new microcuvette and repeat the measurement.
Measurements on patient samples are higher or lower than anticipated.	1. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 2. The optical eye of the microcuvette is contaminated. 3. Air bubbles are present in the microcuvette. 4. The optronic unit is dirty. 5. The calibration of the analyzer has been changed.	1. Check the expiration date and the storage conditions of the microcuvettes. 2. Remeasure the sample with a new microcuvette. 3. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 4. Clean the optronic unit, as described in the Maintenance section. 5. The analyzer needs service. Call your distributor.

Appendix D – HemoCue 301 Troubleshooting Guide

Troubleshooting

If problem remains after recommended actions below are taken, contact the HemoCue distributor or HemoCue AB. The analyzer should be cleaned prior to service, see section *Maintenance* for instructions. If any spare parts are lost or damaged, see section *Components*.

Do not open the cover of the analyzer. Warranty is void if analyzer has been opened.

** Follow relevant section in this operating manual.*

Error Code	Explanation	Action
Error code is displayed.	May be a temporary fault or faulty electronics/optical parts.	Turn analyzer off. Turn on after 30 seconds. If the problem continues, see specific error code below or the analyzer needs service.
E00	1. Faulty microcuvette. 2. Internal error in analyzer.	1a. Check expiry date. 1b. Fill a new microcuvette and perform measurement. * 2. Clean optical parts. *
E01–E02	1. Dirty optical parts. 2. Analyzer too hot/cold.	1. Clean optical parts. * 2. Turn analyzer off, allow to reach operating temperature before use.
E03	1. Analyzer exposed to direct light.	1. Avoid direct light exposure.
E05, E06	1. Analyzer too hot/cold or exposed to direct light.	1a. Turn analyzer off, allow to reach operating temperature before use. 1b. Avoid direct light exposure.
E07	1. Battery power too low.	1a. Batteries need to be replaced. * 1b. Use power adapter.
E08	1a. The absorbance is too high. 1b. Faulty microcuvette or sample. 1c. Dirty or blocked optical parts.	1a and 1b. Ensure analyzer and microcuvettes are used according to operating manual and relevant package insert. 1a and 1c. Clean optical parts. *
E10-E30	1. Internal error in analyzer.	1. Clean optical parts. *

Troubleshooting

Measuring Deviations	Explanation	Action
HHH	1. Result exceeds measuring range.	1a. Fill a new microcuvette and perform measurement. * 1b. Confirm result with laboratory method.
No characters displayed	1. Analyzer not receiving power. 2. Faulty display.	1a. Ensure power adapter is properly connected and cable not damaged. 1b. Batteries need to be replaced. * 2. Analyzer needs service.
Erroneous characters displayed	1. Faulty display/electronics.	1. Analyzer needs service.
The display shows "FIR"	This function is for manufacturing use only.	1a. Replace all cables and/or batteries, and restart. 1b. Analyzer needs service.
is displayed	1. Low battery. 2. Faulty power adapter.	1. Batteries need to be replaced. * 2. Ensure power adapter is properly connected and cable not damaged.
and "Hb" continuously displayed	1. Faulty cuvette holder/analyzer.	1. Analyzer needs service.
Unexpected patient or control results	*Patient sample and control solution* 1. Microcuvettes expired, damaged or improperly stored. 2. Microcuvette contaminated. 3. Dirty optical parts. 4. Air bubbles in filled microcuvette. 5. Faulty optical parts. 6. Incorrect sampling technique. 7. Measurement started later than 40 seconds after filling the microcuvette. *Control solution* 8. Control solution not compatible. 9. Inproper handling of control solution. 10. Control solution expired or improperly stored.	*Patient sample and control solution* 1. Check expiry date and storage conditions. 2. Fill a new microcuvette and perform measurement. * 3. Clean optical parts. * 4. Fill a new microcuvette and perform measurement. * 5. The analyzer needs service. 6. Fill a new microcuvette and perform measurement. * 7. Start measurement no later than 40 seconds after filling the microcuvette. *Control solution* 8. Only use control solutions recommended by HemoCue. 9. Always follow instructions for use for control solution. 10. Check expiry date and storage conditions.

Appendix E – McKesson Consult Troubleshooting Guide

TROUBLESHOOTING GUIDE

Symptom	Possible Cause	Correction
Unexpectedly high / low results	Improper sample	Repeat the sampling. Make sure that the sampling is done correctly. See pages 12 – 15 for more information.
Error E01	Calibration lost	Contact Technical Support at 1-800-531-5535.
Error E02	Sensor read error	Repeat measurement with the same cuvette. If error persists, contact Technical Support at 1-800-531-5535.
Error E03	Self-check failed	E03 may be displayed if a filled cuvette is left in the cuvette holder, or was removed too slowly. In order to reset the self-check function, press down on the empty cuvette holder. The screen should display "---" and a "√". If error persists, contact Technical Support at 1-800-531-5535.
Error E04	Light source too dark	Remove cuvette from cuvette holder. Press cuvette holder several times until the screen reads "---" and a "√" appears. If error persists, contact Technical Support at 1-800-531-5535.
Error E05	Light source too bright	Remove cuvette from cuvette holder. Press cuvette holder several times until the screen reads "---" and a "√" appears. If error persists, contact Technical Support at 1-800-531-5535.
Error E07	Battery too low to perform measurments	Recharge the battery.
Display blank, measuing not possible	Battery completely discharged	To recharge the battery, connect with a power outlet or computer and charge for a minimum of 4 hours.If recharging fails, contact Technical Support at 1-800-531-5535.

Appendix F – Masimo Pronto Troubleshooting Guide

Masimo Pronto Troubleshooting Guide

Problem	Possible Cause(s)	Recommendation(s)
Difficulty or No SpHb Reading (Including Low SIQ)	Coiled / Twisted Sensor Cable	Uncoil / Untwist sensor cable
	Soiled Sensor	Clean sensor with soap and water solution
	Participant wearing metallic, acrylic, or dark fingernail polish	Move sensor to another finger or obtain Hgb value via capillary sampling test
	Inappropriate Sensor/Finger Selection	Verify that appropriate finger and sensor are chosen
	Excessive Motion	Minimize or eliminate motion at the measurement site
	Low Perfusion Index (less than 1.0)	Warm Hands / Choose Another Finger on Other Hand
	Excessive Ambient Light	Shield the sensor from excessive light
Unit does not Power On	Low Battery	Check / replace batteries
Sensor Fails to Initialize (Circulating LEDs)	Incorrectly connected sensor cable	Disconnect and reconnect sensor cable from the patient cable.
Continuous Speaker Tone	Internal Failure	Return Masimo Pronto for Service
Buttons don't work when pressed	Internal Failure	Return Masimo Pronto for Service

Appendix G – CLIA Laboratory Certification Procedures

CLIA Laboratory Certification Procedures

The Local Agency Director or designee is responsible for obtaining and maintaining a Certificate of Waiver from the CLIA Laboratory Program in order to verify that the local agency's labs maintain compliance with federal Clinical Laboratory Improvement Amendment (CLIA) regulations.

There are 6 steps necessary to obtain and maintain Certificates of Wavier. This entire process usually takes 4 to 6 weeks to complete.

Step 1: Complete the CLIA Application Form

Download and complete all sections of the CLIA Application for Certification (link below). For specific instructions regarding the completion of this application, refer to the Laboratory Quick Start Guide (link below) to CLIA Certification.

- Application Form
- Laboratory Quick Start Guide

Step 2: Submit the completed CLIA Application Form

The completed CLIA Application Form must be emailed or faxed to the ADHS Office of Laboratory Licensing and Certification for processing using the information below:

Email: Marcie Bentley
FAX: (602) 364-0759

If necessary, visit the website, call the phone number, or send mail to the address listed below for additional information regarding CLIA certification:

Website
PHONE: (602) 364-0720
Address: ARIZONA DEPARTMENT OF HEALTH SERVICES
Division of Public Health Services
Office of Laboratory Licensing and Certification
250 N. 17TH Avenue Phoenix, AZ 85007

Step 3: Receive Fee Coupon

The Fee Coupon includes information such as your local agency's CLIA identification number, payment due date, and amount due in order to receive/maintain CLIA Certification.

Step 4: Pay applicable fees

Fees may be paid using a debit or credit card by visiting the online U.S. Treasury Platform, or by mailing a check to the address listed below. If writing a check, be sure to include the CLIA identification number and allow 10 business days for processing.

Website

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

Step 5: Receive CLIA Certificate.

Keep this certificate on file and send a copy to your Local Agency's Arizona WIC Nutrition Consultant on years that it has been renewed, as part of the annual Local Agency contract requirements.

Step 6: Maintain CLIA Certificate

CLIA Certificates of Waiver are valid for two years. Six months prior to the end of the certification period, a renewal invoice will be sent. The aforementioned steps must be followed before the expiration period indicated on the renewal invoice in order to prevent a lapse of CLIA Certification.

The ADHS Office of Laboratory Licensing and Certification must be notified within 30 days, any changes to the laboratory director, address, mailing address, phone, fax, email, facility name, and or tax ID previously indicated to obtain a CLIA certificate, using the following change form.

Change Form