REQUIRED GUIDANCE



Policy and Procedure Manual

Volume 1, Chapter 10
Hematology

Washington State WIC Nutrition Program

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Hematology

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Section 1: Definitions and References

Definitions

Applicant: A person, not currently receiving WIC benefits, who comes to the WIC clinic requesting WIC services.

Capillary sampling method: Pricking the skin of the finger (middle or ring) or heel to obtain a blood sample from tiny blood vessels near the surface of the skin.

CDC: Centers for Disease Control.

CLIA: Clinical Laboratory Improvement Amendments. Congress passed CLIA in 1988 to establish standards for laboratory testing.

CLIA-waived: Laboratory tests that the FDA exempted from CLIA requirements because they are simple and have low risk of harm to the patient. An example of a CLIA waived test is the HemoCue test.

CLSI: Clinical and Laboratory Standards Institute.

Deferral: Staff may defer the blood test or obtain results from providers up to 90 days from the date of the certification for applicants with at least one other qualifying nutrition risk.

Exception: Staff don't need to test participants who meet one or more of the following criteria:

- 1) A medical or serious skin condition where testing would cause harm to the participant,
- 2) Religious beliefs that don't allow blood testing, or
- 3) Refusal to test.

Invasive hematology tests: Tests that require staff to puncture the skin. An example of this test is using the HemoCue device to test blood obtained through skin puncture with a lancet.

Medical Test Site License: The type of testing performed determines the MTS/CLIA license category. Select from the following four options: Waived, PPMP, Categorized or Accredited as defined here: <u>Licensing Information | Washington State Department of Health</u>.

Non-invasive blood tests: Tests that don't require staff to puncture the skin. An example is using the Masimo Pronto device to test blood hemoglobin using light technology.

OSHA: Occupational Safety and Health Administration.



Participant: A person who currently receives WIC benefits.

WHO: World Health Organization.

References

Code of Federal Regulations (CFR):

- Required nutritional risk data §246.7 (e)(1)(ii)(B)—Hematological test for anemia
- CLIA Requirements for a Certificate of Waiver—§493

Washington State Medical Test Site Laws: WAC 246-338 and RCW 70.42

Washington State <u>Senate Bill 5244</u> exempts WIC from medical assistant laws: <u>WAC 246-827</u> and <u>RCW 18.360</u>.

Washington State WIC Policy and Procedure Manual chapters that reference bloodwork and record retention:

- Volume 1, Chapter 11 Assessment
- <u>Volume 1, Chapter 12</u> -Referrals
- Volume 1, Chapter 14 Nutrition Risk
- Volume 2, Chapter 7 Record Retention
- Volume 2, Chapter 2 Nutrition Services Plan

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Section 2: The WIC Clinic as a Medical Test Site (MTS)

REQUIRED GUIDANCE: Obtain a Medical Test Site License

Local agencies who perform invasive hemoglobin testing must have a medical test site license as required by state law (WAC 246-338, Medical Test Site Rules).

PROCEDURE:

Agencies obtain a Medical Test Site license by:

- A. Adding the WIC clinic to an existing local agency Medical Test Site license, or
- B. For local agencies who only perform Hemoglobin CLIA waived tests, applying for an MTS CLIA-Waived Certificate here: Medical Test Sites (MTS) Licensing | Washington State Department of Health.

Note: The fee for applying for the MTS for WIC agencies is waived. Local agencies must renew the MTS license every two years.



Section 3: Who May Perform Blood Testing

REQUIRED GUIDANCE: Only Trained Staff May Perform Invasive Blood Testing

Local agency staff who perform bloodwork must complete the following training before performing blood testing:

- 1. DOH STATE WIC Hematology Curriculum in the learning center.
- 2. DOH STATE WIC Bloodborne Pathogens Training in the learning center (annual requirement).
- 3. Review of the local agency exposure control plan.
- 4. Initial Anthro/lab measurement observations.

PROCEDURE:

- A. Certifiers must successfully complete the certifier competency training and be recognized as a WIC Competent Professional Authority (CPA).
- B. Other staff must complete the required training and observations and be certified as competent prior to testing or training others.

Note: WIC is exempt from the Medical Assistants law: <u>WAC 246-827</u>.

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Section 4: When to Perform Blood Testing

REQUIRED GUIDANCE: Test Blood Hemoglobin According to Timing Schedule

Staff must perform blood testing according to the following timeline:

	Blood work Requirement	When to perform the test or receive the value from referral sources	Notes:
Infants 0-5 months	Not required		Staff may test infants between 4 and 6 months when an infant is fully breast or chest feeding or premature and not taking supplemental iron.
Infants 6-12 months*	One test	Test during any appointment where the infant is physically present between 6 and 12 months old.	 Staff can perform the test more than 90 days after Initial certification. If the infant subsequent certification occurs before the first birthday, staff can use this result to meet the requirement of the 6 – 12-month test.
Children 1-5 years old	One test each year	Within 90 days of certification. Test 6 months after the infant test, if possible. When the previous value was low, staff must do follow-up blood tests every 6 months until the value returns to the normal range.	 Staff can't use blood tests, completed before the infant turns one, to meet the requirement for the 1 to 2-year-old test. If the infant to child subsequent certification occurs after the infant turns one, the blood test completed at this appointment counts as the 1 to 2-year-old test.
Presumptively eligible (PE) participant	One test	Within 90 days of PE certification.	Recommended at the Complete Assessment.



	Blood work	When to perform the	
	Requirement	test or receive the value	Notes:
		from referral sources	
Pregnant	One test during	As early as possible in	 Recommended at the
Participant	the current	the pregnancy, and	initial or subsequent
	pregnancy.		certification for a new
		Within 90 days of	pregnancy.
		certification.	
Breast or chest	One test	4-6 weeks after the end	 Recommended at the
feeding and		of the pregnancy, and	Initial or subsequent
Postpartum			certification.
Participant		Within 90 days of	When the IC or SC is within
		certification.	4 weeks of delivery, staff
			schedule a follow up
			appointment to complete
			hemoglobin testing.
			 Breast or chest feeding
			participants who are 6 - 12
			months postpartum don't
			need another blood test if
			they had a test after the
			birth of their infant or
			termination of their
			pregnancy.

^{*} Washington WIC allows bloodwork between 6 and 9 months, although not required by federal regulation.



Section 5: Exceptions

REQUIRED GUIDANCE: Provide Exceptions

Staff must grant exceptions to hematology testing for the following reasons:

- 1. The participant has a medical condition like hemophilia, or a serious skin disease in which the procedure would cause harm to the participant. The participant can self-report the condition.
- 2. Religious belief.
- 3. Not required by policy (for example, the infant is 0 6 months old).
- 4. Refusal.

PROCEDURE:

The CPA:

- A. Documents the exception reason in the Anthro/Lab screen in the participant's file.
- B. Issues three months of food benefits (as appropriate) to participants who have an exception reason.

Information:

Best practice is to ask clarifying questions about a refusal for test. Ask the participant if they are more comfortable getting the test from their healthcare provider and bring results back.



Section 6: Deferral Reasons

REQUIRED GUIDANCE: Defer Testing

Staff may defer hemoglobin testing for up to 90 days of the date of certification for the following participants:

- 1. Participants with at least one nutritional risk factor present at certification.
- 2. Presumptively eligible participants with at least one qualifying risk factor.

PROCEDURE:

- A. Document the following deferral reasons in the Anthro/Lab screen in the participant's file when staff can't perform the test, or staff don't have results from a referral source.
 - 1. Will get results from the medical provider
 - Illness
 - 3. Couldn't get a value
 - 4. Participant not present (Don't use if staff select "no" for physical presence in the participant demographic screen).
 - 5. Equipment failure

Note: Cascades doesn't allow staff to select a Deferred Reason for two consecutive certifications when staff didn't enter values during the previous certification period.

- B. Document efforts to obtain bloodwork values for each participant in a Family Alert.
- C. Issue three months of food benefits to participants who have a deferral reason.



Section 7: Exposure Control

REQUIRED GUIDANCE: Implement Controls to Reduce Staff Exposure to Bloodborne Pathogens

The local agency must:

- 1. Comply with Washington state and OSHA standards. (<u>WAC 296-823-12005</u> and <u>29 CFR 1910.1030</u>).
- 2. Write an exposure control plan to eliminate or minimize exposure to bloodborne pathogens and review the plan annually (WAC 296-823-11010).
- 3. Use controls to eliminate or minimize occupational exposure to blood (<u>WAC 296-823-140</u>).
- 4. Provide personal protective equipment to staff performing invasive blood testing.
- 5. Document exposures according to WAC 296-27-01109 using OSHA form 300.

The Competent Professional Authority (CPA) must:

- 1. Use "Universal Precautions" when performing invasive blood testing to prevent the spread of infectious diseases from bloodborne pathogens.
- 2. Dispose of lancets and microcuvettes in sharps containers.
- 3. Dispose of waste, such as gauze, gloves, and bandages that are not soaked with blood in regular trash.
- 4. Dispose of infectious and blood-soaked waste in a biohazard bag.

Note: CPAs can only perform invasive Hgb tests if they have completed all training and observation requirements. See <u>Section 3: Who May Perform Blood Testing</u>, in this chapter.

PROCEDURE:

The coordinator:

A. Has a written exposure control plan and update the plan annually. Make a copy of this plan available to employees at the work site (<u>WAC 296-823</u>).



- B. Provides annual training on bloodborne pathogens and universal precautions and maintains training files for four years after the date of the training (WAC 296-823-120).
- C. Implements controls to minimize employee exposure (WAC 296-823-140).
- D. In the event of an exposure, refer to the following (<u>WAC 296-823-140</u>) and contact the state WIC office.
- E. Disposes of sharps containers according to OSHA guidelines.

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Section 8: Perform the Hemoglobin Test

REQUIRED GUIDANCE: Perform Tests or Obtain Values from Referral Sources

WIC staff must:

- 1. Perform the invasive or non-invasive test according to manufacturer instructions and Washington State laws, or
- 2. Attempt to obtain hematocrit or hemoglobin values from referral sources within 90 days of the certification except for infants who require a test between 9 and 12 months old.
- 3. Document attempts to get blood values in a family alert.

Notes:

Staff may follow up on blood values at 60 days to align with the timeline for obtaining height and weight measurements.

WIC staff must complete training in the use of invasive and non-invasive equipment prior to testing participants.

PROCEDURE:

Trained WIC staff:

A. Talks to the participant or caregiver about the hemoglobin test. This includes a brief overview why WIC does the test and how. It's important to mention that WIC uses the test to screen participants, not diagnose. The results will also guide the recommendations for dietary changes.

Example:

"The hemoglobin test tells us if you or your child's blood has enough iron. Iron is important for your child's growth (you and your baby's health if you are pregnant, your health if you are breast or chest feeding or post-partum). To do the test, I will:

• Invasive blood test script: "Prick your child's finger to get a drop of blood to test if your child has enough iron. If the test result is low, we'll talk about ways to increase iron in the diet and recommend that your child see their health care provider for follow-up.."



- Non-invasive script: "Put this sensor on your finger. The sensor
 will measure the amount of iron in your blood. It usually takes a
 couple of minutes to get the test results. If the results are low,
 we'll talk about ways to increase iron in your diet and recommend
 that you see your health care provider for follow up."
- B. Uses standard precautions for invasive testing to minimize exposure to blood borne pathogens (See <u>Section 7, Exposure Control</u>).
- C. Follows manufacturer guidelines when performing tests.
 - HemoCue® Hb 201 Operating manual: Hb-201-DM-Operating-Manual.pdf (hemocue.us) located on the <u>Local Agency SharePoint site</u>.
 - HemoCue® Hb 301 Operating manual: HB-301_Operating-Manual_US.pdf (hemocue.us) located on the <u>Local Agency SharePoint site</u>.
 - Masimo Pronto® Pulse CO-Oximeter® Operator's Manual: <u>Pronto (masimo.com)</u>.
 Staff should clean the device when visibly dirty and before and after each procedure.
- D. Perform the invasive test when not able to get a value using non-invasive testing.
- E. Attempt to get values from referral sources and document the attempt in a Family Alert.

Information:

Guidelines for Finger and Heel Sticks

HemoCue recommends the Clinical and Laboratory Standards Institute (CLSI) guidelines, standard GP42-Ed7, for blood collection. This standard requires the finger stick for infants weighing more than 10 kg (22 lbs.) with a lancet depth that isn't more than 1.5 mm.

WHO Guidelines for drawing blood outline conditions for selecting heel or finger stick:

Condition	Heel-stick	Finger stick
Age	Birth-6 months	> 6 months old
Weight	~3-10 Kg (22 lbs.) and not walking	>10 Kg (22 lbs.)
Placement of Lancet	Medial or lateral plantar surface	On the side of the ball of the finger perpendicular to the lines of the fingerprint
Recommended Finger	Not applicable	Second and third finger (middle & ring)

(WHO, 2010).

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WHO guidelines recommend the following Lancet depths:

1.5 mm for: Finger stick for infants and children less than 8 years old.

2.2 mm for: Infant heel and adult finger stick.

The Clinical and Laboratory Standards Institute guidelines suggest, in addition to the heel stick, the big toe as a suitable test site for infants. The lancet depth for the big toe should not exceed 1.5 mm.

Trained WIC staff must use a similar preparation for heel and toe sticks as stated in the manufacturer guidelines for the finger stick.



Section 9: Document Results

REQUIRED GUIDANCE: Document Test Results Performed or Obtained from Referral Sources

Staff must document the test results, or the reason for exception or deferral on the Anthro/Lab screen in Cascades.

PROCEDURE:

The CPA:

- A. Documents the following in the participant's file on the Anthro/Lab screen:
 - 1. Test results: value and date performed.
 - a. Don't accept results from health care providers that are older than 90 days.
 - b. Any staff can record values obtained from referral sources in the participant's file.
 - 2. Exception reasons, if applicable.
 - 3. Deferral reasons, if applicable.
 - 4. Nutrition risk Cascades automatically assigns low and very low hemoglobin or hematocrit risks.

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Section 10: Determine Nutrition Risk

REQUIRED GUIDANCE: Determine Nutrition Risk and High-Risk Status Based on Hemoglobin or Hematocrit Values, Tailor Nutrition Education, and Refer Participants to Health Care Providers

The CPA must:

- 1. Assess blood test values for nutrition risk and high-risk status using the Washington State WIC nutrition risk criteria.
 - See Volume 1, Chapter 14 Nutrition Risk Criteria.
- 2. Tailor nutrition education based on the risk and participant's needs.
- 3. Refer participants with very low hemoglobin/hematocrit value to the WIC Nutritionist and health care provider.

PROCEDURE:

The CPA:

- A. Compares hemoglobin test results to Washington WIC nutrition risk criteria, Federal Risk 201, Low Hematocrit/Low Hemoglobin.
 - See Volume 1, Chapter 14 Nutrition Risk Criteria.
 - See the nutrition risk factor tool, hematology tables tab.
- B. Confirms the test completion date is within the participant's current category.

Notes:

- Examples: Use a value taken during pregnancy for a pregnant participant, or a value taken after delivery for a breast or chest feeding or postpartum participant.
- Values obtained from the medical provider can't be more than 90 days old.
- C. Verifies to make sure Cascades assigns the correct risk. Cascades automatically calculates and assigns risk based on blood test values taken within the past 90 days.
- D. Talks with the participant or caregiver about the results of the test and tailors nutrition education messages.



E. Refers participants with very low hemoglobin/hematocrit values to the WIC nutritionist and the health care provider.

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RECOMMENDATION: Assess Iron for Transfer Participants

When a transfer participant doesn't have a blood test value, it's recommended to perform the blood test or obtain the value in writing from the health care provider.

BEST PRACTICE:

Staff:

- A. Review and document the participant's transfer information.
 - See <u>Volume 1</u>, <u>Chapter 21 Transfers</u> for required documentation.
 - See Volume 1, Chapter 14 Nutrition Risk Criteria.
- B. Schedule a follow-up for the next month to assess the participant's iron status and determine nutrition education and referral needs.
 - 1. Request the transfer participant's previous clinic measurements and blood test values.
 - 2. If there is no blood test value, staff can perform the blood test or obtain the value from the health care provider.
- C. Assess the participant's iron status at the subsequent certification according to policies and procedures in this chapter.
- D. Issue benefits as needed.
 - 1. Staff don't need to limit benefit issuance to monthly for transfer participants with missing blood test values.



Section 11: High Hemoglobin or Hematocrit Results

REQUIRED GUIDANCE: High Hemoglobin or Hematocrit Assessment and Intervention

The CPA must follow the interventions below when they assess the participant's hemoglobin or hematocrit value as "high".

PROCEDURE:

The CPA:

- A. Determines if the participant's hemoglobin or hematocrit is high. A value at or above 14.6 g/dl, or 44% respectively, for pregnant, breast or chest feeding, and postpartum people, infants, and children is high.
- B. Asks the participant if there is a history of high hemoglobin or hematocrit results.

Note: A high hemoglobin or hematocrit may be normal in some instances. Two examples of normal high hemoglobin or hematocrit values include when the body compensates for smoking or living at a high altitude.

- C. Does the following, based on the information from the participant.
 - 1. Documents in the notes that the value is normal for the participant, as reported by the participant.
 - 2. Refers the participant to a health care provider if there is no history of a high value and the hemoglobin is at or above published values.
 - 3. Refers the participant to a health care provider if there is a history of a high hemoglobin or hematocrit <u>and</u> the value is above the participant's "normal" level or is well above published values.
- D. Documents all information discussed with the participant in the Cascades individual care plan.
- E. Plans follow-up as appropriate.

Information:

A high hemoglobin or hematocrit can indicate a medical problem and the CPA should refer these participants to their healthcare provider for follow up and treatment.

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Section 12: Maintain Hematological Equipment

REQUIRED GUIDANCE: Maintain Hematological Equipment

Staff must:

- 1. Clean and maintain hematological equipment as specified in the manufacturer's operating manual and document on the <u>Hemoglobin Machine Maintenance Log</u>.
- 2. Contact the manufacturer if the equipment is less than a year old to repair or replace if it isn't operating according to the manufacturer's specifications.
- 3. Contact <u>WICHematology@doh.wa.gov</u> to place a new order to replace any non-functional equipment when it's more than a year old.

PROCEDURE:

Staff:

- A. Follow the manufacturer's instructions for cleaning and maintenance.
 - 1. Hemocue
 - Operating manual: Hb-201-DM-Operating-Manual.pdf (hemocue.us) located on the <u>Local Agency SharePoint site</u>.
 - Daily Cleaning video: <u>HemoCue 201 DM Systems Cleaning</u> (<u>youtube.com</u>). Use mild detergent, not alcohol.
 - 2. Masimo Pronto
 - Operator's Manual: <u>Pronto (masimo.com)</u>. Staff should clean the device when visibly dirty and before and after each procedure.
- C. Document cleaning and maintenance in the <u>Hemoglobin Machine Maintenance Log</u> and maintain in local agency files for four years.
- D. Repair or replace the equipment when it isn't operating correctly.
 - 1. Contact the manufacturer to troubleshoot the problem.
 - 2. If the analyzer is within 1 year of the purchase date, follow the warranty instructions in the respective operator's manuals.



- 3. If the analyzer is outside of the 1-year warranty and cannot be repaired, dispose of it according to the county and local agency electronic waste disposal policy.
- 4. Report any equipment problems to WIC staff at <u>WICHematology@doh.wa.gov</u> or follow ordering procedures to order replacements.

Information:

It's important to keep the equipment in good working order to assure it's accurate and safe for staff using the equipment.

The HemoCue analyzer performs an automatic self-test each time it is turned on and every 2 hours while the analyzer remains on.

Remove the batteries when not in use.

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Section 13: Order Hematology Supplies

REQUIRED GUIDANCE: Order Hematology Supplies from WIC

Washington WIC provides agencies with hematology supplies at no charge to the agency.

Staff must:

- 1. Order hematology supplies using the online <u>Hematology Order Form</u>.
- 2. Confirm that the packing slip, the shipped items, and the original order agree.
- 3. Send a signed, dated copy of the packing slip to the state WIC office within three days of receiving the shipment.
- 4. Contact <u>WICHematology@doh.wa.gov</u> for instructions when the HemoCue analyzer or Masimo Pronto device needs repair or replacement.

Using Liquid Controls is <u>not</u> a required procedure for HemoCue Analyzers. Agencies who wish to use controls can't use WIC funding sources to purchase them.

Note: Washington WIC only provides the supplies listed on the order forms.

PROCEDURE:

Staff:

- A. Order hematology supplies in the amount needed for 6 months using the following guidance:
 - 1. Estimate the number of supplies needed for 6 months based on participating caseload and percentage of Hemocue and/or Masimo tests you complete.
 - 2. Use the HemoCue microcuvettes following this guidance:
 - The Hemocue 201+ cuvette vials expire 90 days after opening the vial.
 Use all the cuvettes by the expiration date on the package.
 - The Hemocue 301 cuvette vials don't expire after opening the vial. Use all the cuvettes by the expiration date on the package.
 - Use all the individually wrapped cuvettes by expiration date on the package.



3. Masimo sensors are available in pediatric and adult sizes. The sensors don't have expiration dates.

Note: Ordering hematology supplies twice a year is preferred to reduce costs, but staff can order more often when necessary.

- B. Order hematology supplies.
 - Use the online Hematology Order Form to order hematology supplies.
 - 2. Order HemoCue and Masimo supplies a month before you need the supplies to allow for ordering and shipping delays. State staff place orders the last week of each month.
 - 3. Receive order confirmation. If you don't receive confirmation, please email WICHematology@doh.wa.gov.
- C. When agency staff need supplies immediately, clinic staff may use supplies from another local WIC agency.
- D. Confirm that the packing slip, the items shipped, and the original order agree.
 - If the order is correct and complete write "complete" on the packing slip.
 - 2. If the order is incomplete or incorrect:
 - a. Write on the packing slip which items were incomplete or incorrect and describe what was wrong or not delivered.
 - b. Contact <u>WICHematology@doh.wa.gov</u> for guidance about what to do with the incorrect items.
 - c. If you did not receive all the items you ordered, but the items on the packing slip and what you received match, write on the packing slip "partial order".
 - 3. If you receive a backordered shipment of supplies that completes a previous partial order, write "partial order now complete" on the new packing slip.
- E. Then, send a signed, dated copy of the packing slip by email to WICHematology@doh.wa.gov within three days of shipment delivery.

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Note: State WIC staff must receive all packing slips to pay the invoices and place additional orders.

- F. Keep the original packing slips on file for 6 years.
- G. Contact WICHematology@doh.wa.gov if you need to exchange or return supplies.
- H. When you need to repair or replace HemoCue or Masimo Analyzers, contact WICHematology@doh.wa.gov.

Information:

Local Program Consultants can help agencies estimate quantities of hematology supplies. Contact <u>WICLPC@doh.wa.gov</u> for support.

State WIC Staff may change ordering procedures as our contractors update products and contracts change. Email <u>WICHematology@DOH.wa.gov</u> with any questions.