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Document History:

Title:	**HemoCue® WBC POCT Mini Verification Protocol**	**Site(s):**	**Sites Approved by Shared Health Hematology Medical Director**

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Section:	**Hematology**	**Subsection:**	**POCT Laboratory**

Approved by: **Signature:**	Dr. Ping Sun *(signature on file)*	**Date:**	28-Sept-2021
		Effective Date:	04-Nov-2021

Details of Recent Revision

- Update process states that a patient consent is not required if a physician orders a CBC test (page 3-4)

HemoCue® WBC POCT Verification Protocol

Purpose: This verification protocol provides instructions to verify that the WBC results obtained by each handheld device and microcuvette are comparable to the WBC results obtained from a venous EDTA specimen processed on the CBC analyzer in a Hematology Laboratory.

The verification of performance should provide evidence that the accuracy, precision, and reportable range are adequate to meet the needs of the patient population and clinicians as determined by the Medical Director.

This SOP is to be used when another handheld device is already in use or if a replacement device has been received.

Policy: Each handheld is a test system and must be verified before use.
The HemoCue® WBC is intended for the measurement of WBC.

Materials:

Reagents	Supplies	Equipment
	• HemoCue® WBC microcuvettes • Lancets • Plastic syringes • Gauze/lint-free wipes • Alcohol swab • Plastic pipette	• HemoCue® WBC System device

Sample: A minimum of five (5) patients shall be selected by the laboratory to participate in the comparison process. The following scheme is recommended.

Target WBC Value	Number of patients
$\leq 5.0 \times 10^9$/L	Min of 2
5.0 – 15.0 x 10^9/L	Min of 1
$> 15.0 \times 10^9$/L	Min of 2

Special Safety Precautions: Follow Routine Practices. Mandatory use of gloves and safety glasses required.

Process: Follow the activities in the table below to perform the verification study. Collection method must be established prior to start of verification. Collection methods include capillary (finger puncture) or venous.

Note: Patient consent is not required if the physician (healthcare practitioner) has ordered a CBC test.

Testing Familiarity:

Step:	Action:
1	The individuals performing the tests should be thoroughly familiar with the operation, maintenance and quality control procedures as well as storage conditions and preparation of consumables for the test and comparative methods before starting the protocol. • See HemoCue® WBC System, 140-170-04. • All individuals must have completed initial training and be signed off prior to performing any testing. • A variation of operators is required.
2	A precision study must be performed. See Procedure A: Precision Study. The values are inserted into F140-170-06B and submitted to the Hematology Technical Director by fax (204-787-4030) or e-mail.
3	For each individual patient, a capillary or venous sample is tested on the HemoCue® WBC handheld device and a concurrent venous blood sample (EDTA) is collected and submitted to the Hematology Laboratory with a Hematology test requisition for WBC testing. See Procedure B; Methodology Comparison **Note:** Patients must sign a consent form prior to blood being drawn only if a CBC test is not ordered by a physician and patient agrees to be part of the validation. Specimens submitted to the laboratory must meet Acceptance Criteria as outlined in the Specimen Acceptance Policy, 10-50-03.
4	A HemoCue® WBC POCT INR Verification Study form (F140-170-06A) must be completed and include the following information: • Patient Identification • Patient permission to collect a capillary (if applicable) and venous sample for the POCT WBC comparison study (if applicable) • Collection date/time for samples • Phlebotomist initials • Venous sample accession number • WBC result of POCT sample and result printout from the handheld device. • WBC result of the venous sample from Hematology Lab • Information regarding problems encountered when collecting the samples

5	Charge Technologist/designate is responsible for compiling individual patient data to HemoCue® WBC POCT Verification Study Data Log (F140-170-06C) and submit to the Hematology Technical Director via fax (204-787-4030) or e-mail.
6	Data to be reviewed by the Provincial Hematology team.
7	A HemoCue® WBC POCT Verification Summary report F140-170-06D will be issued to the Laboratory. The specific WBC result that requires a venous sample to be sent to the Laboratory for confirmation will be included in the report.
8	POCT results must be permanently recorded in the patient's medical chart and must be identified as a POCT result.

Handheld Device Preparation:

Handhelds should be on a level surface and should not be moved during the WBC test cycle.

Before starting this verification, ensure that the clock in each Handheld is correct for your time zone.

Procedure A: Precision Study

Perform as per procedure for testing in HemoCue® WBC System, 140-170-04.

Step:	Action:
1	Test the WBC from **one** CBC patient sample twenty (20) times.
2	Mean, standard deviation (SD) and coefficient of variation (%CV) are calculated
3	Insert values into F140-170-06B, HemoCue® WBC Precision Study Log
4	Submit to Hematology Technical Director.

Procedure B: Methodology Comparison

Perform as per procedure for testing in HemoCue® WBC System, 140-170-04.

Step:	Action:
1	The WBC POCT test should be performed either immediately before or after the venipuncture collection of the EDTA tube. Five (5) sample comparisons are required.
2	Insert the microcuvette into the handhelds immediately after they are filled.
3	The venous sample must be stored/transported refrigerated (2-8°C) and processed within 48h at a laboratory on a CBC analyzer.
4	All study data must be entered onto form F140-170-06C for comparison purposes.

Related Procedures:

Procedure: Specimen Acceptance Policy [10-50-03]
Procedure: HemoCue® WBC System [140-170-04]

Related Documents:

Form F140-170-06A: HemoCue® WBC POCT Verification Study form
Form F140-170-06B: HemoCue® WBC.POCT Precision Study
Form F140-170-06C: HemoCue® WBC POCT Verification Study Data
Form F140-170-06D: HemoCue® WBC Verification Summary Report

Appendix:

Appendix 1: Consent Form

APPENDIX 1

CONSENT FORM

Hematology Laboratory

Voluntary Blood Collection for POCT Verification

I, _____, hereby volunteer and consent to have blood drawn by Laboratory staff and to donate that blood to the laboratory for the purpose of establishing POCT Verification.

I further understand that in accordance with PHIA regulations, my identity and any results from the testing of my donated blood within this control group will remain anonymous to all other than those necessarily requiring this information for control functions.

Signed and witnessed this _____ day of _____, 20__

Signature: _____

Witness to Signature: _____