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Document History:

Title: **HemoCue® Hb 201⁺ POCT Mini Verification Protocol**

Site(s): **Sites Approved by Shared Health Hematology Medical Director**

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Approved by: **Signature:**	Dr. Ping Sun *(signature on file)*	**Date:**	28-SEPT-2021
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Details of Recent Revision

- Updated process which states that patient consent is not required if a physician orders a CBC test (page 2-3)

HemoCue® Hb 201⁺ POCT Mini Verification Protocol

Purpose: This verification protocol provides instructions to verify that the hemoglobin results obtained by each handheld device are comparable to the hemoglobin 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 hand-held 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® Hb 201⁺ is intended for the measurement of hemoglobin.

Materials:

Reagents:	Supplies:	Equipment:
• Eurotrol Hemotrol low, normal, and high controls	• Microcuvettes • Lancets • Glass slide • Gauze/lint-free wipes • Alcohol swab • Plastic pipette	• HemoCue® Hb 201⁺ 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 Hemoglobin Value	Number of Patients	Estimated Hemoglobin Range
low	Min of 2	80 +/- 4
normal	Min of 1	121 +/- 6
high	Min 2	160 +/- 8

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 a 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® Hb 201+, 140-170-03. • 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 F140-170-05B 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® Hb 201+ handheld device and a concurrent venous blood sample (EDTA) is collected and submitted to the Hematology Laboratory with a Hematology test requisition for CBC (hemoglobin) 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® Hb 201+ Verification Study form (F140-170-05A) must be completed and include the following information: • Patient Identification • Patient permission to collect a capillary (if applicable) and venous sample for the POCT hemoglobin comparison study (if applicable). • Collection date/time for samples • Phlebotomist initials • Venous sample accession number • Hemoglobin result of POCT sample and result printout from the handheld device. • Hemoglobin 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® Hb 201⁺ Verification Study Data Log (F140-170-05C) 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® Hb 201⁺ Verification Summary report F140-170-05D will be issued to the Laboratory. The specific hemoglobin 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 hemoglobin 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 hemoglobin controls with Eurotrol Hemotrol low, normal, and high controls. Refer to HemoCue® Hb 201⁺, 140-170-03.

Step:	Action:
1	Test the hemoglobin value for Level 1, Level 2, and Level 3 controls a minimum of twenty (20) times each.
2	Mean, standard deviation (SD), and coefficient of variation (%CV) are calculated
3	Insert values into HemoCue® Hb 201⁺ POCT Precision Study Log, form F140-170-05B.
4	Submit to Hematology Technical Director.

Procedure B: Methodology Comparison

Perform as per procedure for testing in HemoCue® Hb 201⁺, 140-170-04.

Step:	Action:
1	The hemoglobin 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 24h.
4	Document all hemoglobin results onto HemoCue® Hb 201⁺ POCT Verification Study Data, form F140-170-05C and send to Technical Director for evaluation.

Related Procedures:
Procedure: Specimen Acceptance Policy [10-50-03]
Procedure: HemoCue® Hb 201+ [140-170-03]

Related Documents:
Form F140-170-05A: HemoCue® Hb 201+ POCT Verification Study form
Form F140-170-05B: HemoCue® Hb 201+ POCT Precision Study Log
Form F140-170-05C: HemoCue® Hb 201+ POCT Verification Study Data
Form F140-170-05D: HemoCue® Hb 201+ 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: _____