

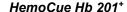
Document History:

Title: HemoCue Hb 201 Site(s): All Applicable Sites

Document #:	140-170-03	Version:	07
Section:	Hematology	Subsection:	POCT Laboratory
		•	
Approved by:	Dr. Ping Sun (Approval on file)	Date:	7-SEPT-2022
		Effective Date:	1-OCT-2022

Details of Recent Revision

- Update to Quality Control section (requirements, comparisons, new lots/shipments)
- Update to Related Documents
- Update to Procedural Note #3
- Clarify Critical Value (≤ 65 g/L)
- Addition of Procedure Note 4: When Confirmatory Testing Can't be Sent to Referral Site
- Addition of LIS Worklist
- Update to Policy regarding confirmatory testing





HemoCue® Hb 201⁺

Purpose: This procedure provides instructions for determining the hemoglobin value on this point of care

device.

Policy: This unit can be used in the lab or the bedside. The analyzer stores test results, date and time

for up to 600 tests.

This system is used for the determination of the total amount of hemoglobin in whole blood. The system consists of an analyzer with microcuvettes containing dried reagents. The microcuvette acts as a pipette, reaction chamber and as a measuring device. No dilution is required. The hemoglobin measurement occurs in the analyzer, which follows the progress of the reaction until a steady state is reached.

The system is factory calibrated against the hemoglobin cyanide (HiCN) method (the international reference method) and thus requires no further calibration.

Results > 235 g/L or displaying HHH or < 65 g/L will result in confirmatory testing at hematology site.

Materials:

Reagents:	Supplies:	Equipment:
 Eurotrol Hemotrol Low, Normal and High controls Alcohol Mild soap solution 	HemoCue® cleaner Microcuvettes Lacets Pipette or Diff safe Lint-free wipes Hydrophobic plastic or glass slide	 HemoCue® Hb 201+ Printer Cable

Special Safety Precautions:

As per Routine Practices (Standard Precautions). Mandatory use of gloves. Equipment not suitable for use in the presence of flammable mixtures.

Sample:

- Capillary, venous or arterial blood can be used
- EDTA anticoagulated samples can be used
 - Mix all specimen samples 8 10 times by hand inversion.
 - If the specimen has been refrigerated, allow sample to warm up to room temperature before mixing.

Quality Control:

- Eurotrol Hemotrol is an assayed hemoglobin control with a known concentration.
- To be performed prior to testing the first patient sample of the day or at least one (1) time per week if testing not performed daily.
- 10 μL of control material is used per run
- · Each level contains 1 mL of purified bovine hemolysate
- Store unopened in the refrigerator at 2 8 °C until expiration date
- After vial is opened, stability is one month if properly capped and stored at 2-30°C
- Monthly comparison of a previously processed hemoglobin result from HemoCue and main analyzer from a nearby laboratory must be performed. The CBC sample must be less than 24 hours post collection at the time that it is processed on the HemoCue.
 - The comparison results must be within 7%.
- Site must participate in CAP EPT
- New lot numbers or new shipment same lot number of QC or cuvettes requires the QC to be run once and documented on the QC log prior to testing patient samples.
- QC values must be within stated insert ranges.



Self-Test:

Analyzer has an internal quality control or "self-test". When the analyzer is turned on, it will
automatically verify the performance of the optronic unit of the analyzer. This test is
performed every second hour if unit is left on.

If:	Then:
"Self-test" passes,	Screen will display HemoCue® symbol and three flashing dashes indicating the unit is ready to perform testing.
"Self-test" fails,	An error code will appear on the screen

Storage and Handling:

Microcuvettes:

- Must be used prior to the expiration date printed on each package
- Store at room temperature (15 30 °C)
- Do NOT refrigerate
- Expiration date of the microcuvette in a sealed vial is printed on the vial
- Once seal is broken on a vial, stable for three months.
- Keep vial container closed at all times.

Individual Packages of Cuvettes:

- Store at room temperature (15 30 °C)
- Do NOT refrigerate
- Stable until expiry date printed on each individual package

Note: Microcuvette must be filled with blood/QC matrix within three (3) minutes of opening the wrapping.

HemoCue® Analyzer:

- Store at 0 50°C
- Operating temperature is 15 30 °C
- Allow unit to reach room temperature before use
- Should not be used at high humidity (>90%)

Accessioning:

Register the test in Delphic:

- Test code is IHGB (POCT HGB)
- Document LIS sample number onto test requisition

If:	Then:
Test performed by non-DSM laboratory staff,	Order test code POCT (Test performed by non-laboratory personnel)

IMPORTANT: Lab performed tests **CANNOT** be combined with non-lab performed tests on a single registration as the code applies to all tests under a single request ID.

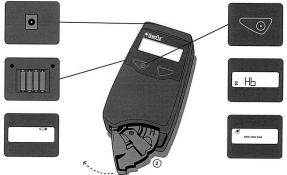
LIS Worklist:

ICBC is printed prior to patient testing to record results and staff details for 2-year retention (with printout as applicable).



Procedure A: Start-Up

Follow the activities in the table below for start-up of the HemoCue.



Step:	Action:
1	Ensure the analyzer is placed horizontally and on a stable surface.
2	A power source is required so either:
	Connect the adapter to the socket at the back and plug it into the outlet or Insert 4 type AA batteries (1.5v) into the battery compartment.
	Note: If a battery symbol appears on the display, the batteries are running low. The analyzer will continue to provide accurate results but the batteries should be replaced immediately.
3	Pull the cuvette holder out to its loading position.
4	Press and hold the left button until the display is activated and all symbols appear on the screen.
5	The display shows the version number of the program, after which it will show
	"E" and "Hb" and "S". The analyzer will automatically start verifying the performance of the optronic unit by performing the self-test.
6	After ten seconds, three flashing dashes and the HemoCue symbol will appear on the screen. These symbols indicate the self-test passed and the unit is ready to use.
7	If the self-test fails, an error code will be displayed.
8	To turn off the analyzer, press and hold the left button until "off" is seen on the screen. The display will become blank. Disconnect the equipment from the power source by removing the adapter from the power source.

Procedure B:

Set-Up of Audio Signal, Time and Date

Set-Up of Follow the activities in the table below for set-up of audio signal, time, and date.

Tollow the activities in the table below for set-up of additionally fine, and date.	
Step:	Action:
1	Time and date function must be activated prior to the unit being used.
2	Press both buttons at the same time. The screen will show a flashing QC symbol.
3	Use the right button to scroll until the screen shows an audio symbol in the upper right corner. The signal can be activated or deactivated by pressing the left button.
4	Using the right button, scroll until the screen show characters for time, date, and year. The hour figure will be flashing.



5		The right button will allow the user to set the hour, minutes, day, month, and year. To change a flashing figure, hold the left button down for quick advancement or press and release the left button quickly to advance slowly.
6	}	Hold the right button down for 5 seconds when the settings are appropriate. The analyzer will automatically return to the measuring position.

Procedure C: Measuring Control Material Follow the activities in the table below to measure control material.

Step:	Action:
1	Allow the vial to stand for 15 minutes at room temperature (15-30°C) if coming from the refrigerator.
2	Control material should be gently mixed well prior to performing any testing (8 – 10 times) by hand inversion.
	Note: The microcuvette must be filled with QC material within three (3) minutes of opening the wrapper.
3	Using a pipette or transfer device (diff safe), place a drop of control material onto a hydrophobic surface (i.e. plastic film or glass slide)
4	Fill the microcuvette in one continuous motion. Do NOT refill! Wipe off any excess control material from the microcuvette with a clean lint-free wipe, ensuring not to touch the open end of the microcuvette.
5	If bubbles are present in the microcuvette, discard and fill a new microcuvette from a second drop of control material. Small bubbles around the edge can be ignored.
6	Place the filled microcuvette into the cuvette holder and start measurement as soon as possible, but no later than ten (10) minutes after filling the microcuvette.
7	Gently slide the cuvette holder to the measuring position.
8	During the measurement phase, "\$\begin{align*} \text{(hour glass)} and three fixed dashes will be seen on the screen.
9	After 15 – 60 seconds, the hemoglobin value will be displayed. This result will remain on the screen as long as the cuvette holder is in the measuring position.
10	Remove the microcuvette from the cuvette holder and discard in an autoclave bag.



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11	If:	Then:
	QC within limit range,	Enter P (pass).Record value in hemoglobin and compare to range.
		If all other QC levels are within limit range, process
		sample.Comment if trends observed.
	QC outside limit range,	 Enter F (fail) in comment. Do not process samples. Inspect QC specimen (ie. volume, open vial expiry date). Repeat QC sample with a new microcuvette. Record value in hemoglobin and compare to range. Comment on actions/resolution.
	Repeat QC outside limit range,	 Do not process samples. Consider instrument problem. Troubleshoot as applicable. If not resolved, notify Supervisor; implement Contingency Plan. Charge Technologist or delegate must investigate and comment on specific corrective actions. Contact technical assistance for help
12	Document hemoglobin resu 10A.	ults on the HemoCue [®] Hemoglobin QC log, form F140-170-

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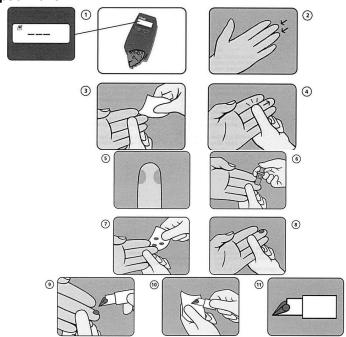
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Procedure D:

Measuring Capillary Blood Follow the activities in the table below to measure capillary blood.

Note: Always handle blood carefully as it could be infectious. Wear gloves when handling blood specimens.



Step:	Action:	
1	After start-up is complete, the cuvette holder will be in the loading position. The screen will show three flashing dashes and the HemoCue® symbol.	
	Note: The microcuvette must be filled with blood within three (3) minutes of opening the wrapper.	
2	Ensure the patient's hand is warm and relaxed prior to starting the procedure. Use either the middle or ring finger for sampling while avoiding any fingers with jewelry on.	
3	Clean the finger with disinfectant and allow to dry or wipe off with a dry, lint-free wipe.	
4	Using your thumb, lightly press the finger from the top of the knuckle towards the tip. This motion will stimulate the blood flow towards the sampling point.	
5	For best blood flow, use the side of the fingertip and not the center.	
6	While lightly pressing towards the fingertip, puncture the finger using a lancet.	
7	Wipe away the first 2-3 drops of blood.	
8	Apply light pressure towards the fingertip until another drop of blood appears.	
9	When blood droplet is large enough, fill the microcuvette in one continuous motion.	
	DO NOT REFILL!	



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10	Wipe away any excess blood from the outside of the microcuvette with a clean, lint-free wipe.	
	Note: Do NOT touch the open end of the microcuvette to prevent blood from being drawn into it.	
11	If air bubbles are present in the microcuvette, discard it and fill a new one from a new drop of blood. Small bubbles around the edge can be ignored.	
12	Place the filled microcuvette into the cuvette holder and start measurement as soon as possible, but no later than ten (10) minutes after filling the microcuvette.	
13	Gently slide the cuvette holder to the measuring position.	
14	During the measurement phase, "\$" (hour glass) and three fixed dashes will be seen	
	on the screen.	
15	After 15 – 60 seconds, the hemoglobin value will be displayed. This result will remain on the screen as long as the cuvette holder is in the measuring position.	
16	If results are unexpected or unacceptable, repeat the test to rule out potential pre- analytical factors as the cause. Perform a second finger poke. Refer to Step 12 Procedure E for additional reporting details.	
17	Remove the microcuvette from the cuvette holder and discard in an autoclave bag.	
18	If the analyzer is operating on battery power, the unit will automatically turn off after five (5) minutes.	

Procedure E: Venous and Arterial Blood

Follow the activities in the table below to measure venous and arterial blood.

Step:	Action:
1	Allow the patient sample to stand for 15 minutes at room temperature (15 $-$ 30 $^{\circ}$ C) if coming from the refrigerator.
2	
	Blood should be gently mixed well prior to performing any testing (8 – 10 times) by hand inversion.
3	Using a pipette or transfer device (diff safe), place a drop of blood onto a hydrophobic surface (i.e. plastic film or glass slide).



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4	Fill the microcuvette in one continuous motion. Do NOT refill! Wipe off any excess blood from the microcuvette with a clean lint-free wipe, ensuring not to touch the open end of the microcuvette.		
	Note: The microcuvette must be filled with blood within three (3) minutes of opening the wrapper.		
5	If bubbles are present in the microcuvette, discard and fill a new microcuvette from a second drop of blood. Small bubbles around the edge can be ignored.		
6	Place the filled microcuvette into the cuvette holder and start measurement as soon as possible, but no later than ten (10) minutes after filling the microcuvette.		
7	Gently slide the cuvette holder to the measuring position.		
8	During the measurement phase, "\$\begin{align*} \text{(hour glass)} and three fixed dashes will be seen on the screen.		
9	After 15-60 seconds, the hemoglobin value will be displayed. This result will remain on the screen as long as the cuvette holder is in the measuring position.		
10	If results are unexpected or unacceptable, repeat the test to rule out potential pre- analytical factors as the cause.		
11	Remove the microcuvette from the cuvette holder and discard in an autoclave bag.		
12	If:	Then:	
	Hbg is < 65 g/L,	Report Hbg result In ICOM comment, insert &HgbP (Preliminary result Hbg result is less than 65 g/L. Venous sample is being sent to reference lab for confirmatory testing) Draw venous sample and send to reference lab for confirmatory testing of Hgb.	
	Hgb is >235 g/L or displays HHH	 Report result or if HHH place *&DEL in the IHGB box. In ICOM enter comment "Preliminary result is >235 g/L. Venous sample is being sent to reference lab for confirmatory testing.) 	

Procedure F: Maintenance Cuvette Holder

Follow the steps in the table below for maintenance of **cuvette holder**. Cuvette holder is stored in the closed position when not in use.

Note: Must be cleaned after each day of use.



Step	Action
1	Turn analyzer off. The screen should be blank.
2	Pull the cuvette holder out to its loading position. Carefully press the small catch positioned in the upper right corner of the cuvette holder.
3	While pressing the catch, carefully rotate the cuvette holder towards the left as far as possible. Carefully pull the cuvette holder away from the analyzer.
4	Clean the cuvette holder with alcohol or mild detergent. It is essential that the holder is allowed to dry completely before being replaced. Do not spray cleaning product directly onto analyzer.
5	Document on HemoCue Maintenance Log.



Optronic Unit Follow the steps in the table below for maintenance of optronic unit and unit cover.

	Step	Action
· · · · · · · · · · · · · · · · · · ·		This unit should be cleaned when directed to do so in the Troubleshooting Guide or once per month. A dirty optronic unit may cause the analyzer to display an error code.
	2	Push the HemoCue cleaner swab into the opening of the cuvette holder.
	3	Move the swab from side to side $5-10$ times. If the swab becomes stained, repeat the process with a new swab. No further cleaning is required if the swab remains clean.
	4	Wait 15 minutes before replacing the cuvette holder and using the analyzer.
	5	As an alternative to Hemocue Cleaner, a cotton tip swab moistened with alcohol (without additive) or water may also be used.
Unit cover	6	The cover can be cleaned with either alcohol or a mild soap solution weekly. Do not spray cleaning product directly onto analyzer.
	7	Document all maintenance performed onto HemoCue® Hb 201 ⁺ Maintenance Log, form F140-170-03B.

Result Reporting:

- 1. Document Hgb result into Delphic by inserting POCT Hgb value from printer tape into IHgb slot on ICBC format.
- 2. Double check IHgb value inserted for transcription errors PRIOR to result release.
- 3. Document any comments in ICOM comment area on ICBC format
- 4. Complete documentation on ICBC worksheet and file.

Expected Values:

Adult males: 130 – 170 g/L Adult females: 120 – 150 g/L

Infants, after neonatal period: 110 - 140 g/L

Children, two years to teenage: Gradual increase to adult normal

Manufacturer does not provide ranges between the ages of children to teenager. Based on the range verification, the values are comparable to standard analyzers and suggest pediatric ranges could be used for these ages.

Interpretation/ Critical Values:

Test	Result	Encounter
Hgb	≤ 65 g/L	First time, same day

Phoning Critical Values: Immediate notification is required when any results of tests exceed established critical values. Report must include person notified (first and last name), test result, verification of "read back" **&RB** of results, date and time in ICOM comment area. Ensure "Read back" is stated to indicate the results were read back.





Measuring

0-256 g/L

Range: Results above 256 g/L will disp

Results above 256 g/L will display HHH which must then be confirmed by sending a CBC sample to the nearest reference laboratory or site-based laboratory. Values above 235 g/L must be confirmed by sending a CBC sample to the nearest reference laboratory or site-based laboratory.

References: HemoCue® Hb 201+ Operating Manual

Related

Documents: Form F140-170-03A: HemoCue® Hb QC Log

Form F140-170-03B: HemoCue® Maintenance Log

Form F100-140-04: HemoCue®/i-STAT Requisition/Report

Job Aid JA100-140-03: HemoCue Hb 201

Appendixes: Appendix 1: Troubleshooting Guide

Procedural Notes:

Procedural Note #1:

Theory:

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The red blood cell membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrate converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin which then combines with azide to form azidemethemoglobin.

Procedural Note #2: Pre-analytical Variables:

- Hemoglobin measurements from capillary sampling may be misleading in cases of peripheral circulatory failure
- Extra cellular fluid present in capillary samples due to patient physiology or unacceptable capillary technique can cause false hemoglobin results.
- Another pre-analytical factor associated with sampling techniques is in regards to the size and proper use of the lancet. Proper technique has a direct effect on the puncture, blood flow, and therefore results obtained.
- Confirmation of an unacceptable or unexpected result is required to rule out potential pre-analytical factors causes. Repeat sample using a second finger poke.
- Keep unit away from portable and RF communication equipment (transmitters)

Procedural Note #3: Retention Policy:

Since all results and QC are not going directly into the LIS using an interface, these results are being manually entered onto a log sheet or into the LIS and therefore must be kept for 2 years as per accreditation. Therefore, place QC results from the ticker tape onto the QC log (if this is what the site wants to use), place the ticker tape onto a plain white piece of paper, scan the image into the computer and keep it in a QC file folder with month and year for easy retrieval or use the requisition or LIS worksheet. The original ticker tape results can then be discarded after it is confirmed that the results have been captured in the computer file. After the 2-year mark, the oldest information can be deleted month by month as time progresses. If one wishes to keep the results in paper format, then photocopy the image of the paper with the results on it and place in a binder under month and year. The issue is that the ticker tape will fade and disappear over time and is useless in less than one year, which doesn't meet accreditation policy.



<u>Procedural Note # 4:</u> <u>When Confirmatory Testing Can't be Sent to Referral Site:</u>

This scenario might occur in some of our sites because: a) techs do not work weekends/STAT days and b) no availability of other couriers than lab truck or volunteer drivers.

In these situations, where a confirmatory testing sample is required for Hemocue results, upon the MLTs return to the lab and after entering the POCT result, free text this sentence in the associated POCT test comment field: "Confirmatory sample is greater than 48 hours old and is not suitable for confirmatory testing."

If your referral site is WL, then the comment would state 72 hours instead of 48 hours because their analyzer has been validated to that timeframe.

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APPENDIX 1

TROUBLESHOOTING GUIDE

If you are unable to resolve the problem by following this Trouble Shooting Guide, please contact HemoCue Inc. The analyzer has no serviceable parts.

Symptom	Explanation	Action
The analyzer shows an error cod	e. May be a temporary 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.
E00	No stable endpoint is found within the time range. 1. The cuvette is faulty. 2. The circuit board is out of order.	1a. Check the expiration date for the microcuvettes.1b. Take a new microcuvette and repeat the measurement.2. The analyzer needs service. Contact HemoCue, Inc.
E01-E05	Dirty optronic unit or faulty electronic or optronic unit.	1a. Turn off the analyzer and clean the optronic unit as described in the maintenance section.1b. The analyzer needs service. Contact HemoCue, Inc.
E06	Unstable blank value The analyzer might be cold.	 Turn off the analyzer and allow it to reach room temperature. If the problem continues, the analyzer needs service. Contact HemoCue, Inc.
E07	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.
E08	The absorbance is too high. 1. An item is blocking the light in the cuvette holder.	Check that the analyzer and microcuvettes are being used according to the HemoCue Hb 201+ operating manual and instructions for use. The analyzer needs service. Contact HemoCue, Inc.
E09-E30	Dirty optronic unit or faulty electronic or optronic unit.	Turn off the analyzer and clean the optronic unit as described in the maintenance section. The analyzer needs service. Contact HemoCue, Inc.
нн	1. Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L).	
***	The analyzer is not receiving power. If on battery power, the batteries need to be replaced. The display is out of order.	1a. Check that the power adapter is connected to the AC power supply. 1b. Check that the power adapter is securely connected to the analyzer. 1c. Check that the cable is not damaged. 2. Turn off the analyzer and replace the batteries, 4 type AA. 3. The analyzer needs service. Contact HemoCue, Inc.
	The display is out of order. The microprocessor is out of order.	The analyzer needs service. Contact HemoCue, Inc. The analyzer needs service. Contact HemoCue, Inc.
	 The batteries need to be replaced. If on mains power, the mains adapter or the circuit board is out of order. 	Turn off the analyzer and replace the batteries, 4 type AA. Check that the power adapter is properly connected and working. The analyzer needs service. Contact HemoCue, Inc.
(B) 40 M (C) (B) 20 M (C) (B) 4 M (C) (B) (B) (B) (B) (B) (B) (B) (B) (B) (B	 The magnet in the cuvette holder may be missing. The magnetic sensor is out of order. 	The analyzer needs service. Contact HemoCue, Inc. The analyzer needs service. Contact HemoCue, Inc.

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Symptom	Explanation	Action
Measurements on control materials are out of range – either too HIGH or too LOW.	 The microcuvettes are beyond their expiration date, damaged or have been improperly stored. The optical eye of the microcuvette is contaminated. The control has not been mixed properly and/or is not at room temperature. Air bubbles in the microcuvette. The optronic unit is dirty. The control is not suitable for use with the HemoCue Hb 201+ system. The calibration of the analyzer has been changed. The controls are beyond their expiration dates or have been improperly stored. 	 Check the expiration date and the storage conditions of the microcuvettes. Remeasure the sample with a new microcuvette. Make sure that the control is mixed properly and at room temperature. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. Clean the optronic unit as described in the maintenance section. Only use controls intended for the HemoCue Hb 201+ systems. Contact HemoCue, Inc. for control information. The analyzer needs service. Contact HemoCue, Inc. Check the expiration date and the storage conditions of the control. Take a new microcuvette and repeat the measurement from a new vial/bottle of control.
Measurements on patient samples are higher or lower than anticipated.	 Improper sampling technique. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. The optical eye of the microcuvette is contaminated. Air bubbles in the microcuvette. The optronic unit is dirty. The calibration of the analyzer has changed. 	 See pages 8–17 in this manual. Check the expiration date and the storage conditions of the microcuvettes. Check the entire system with a commercial control. Remeasure the sample with a new microcuvette. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. Clean the optronic unit as described in the maintenance section. The analyzer needs service. Contact HemoCue, Inc.