Status **Active** PolicyStat ID **13340497**

Sutter Health
Sutter Roseville Medical Center

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Owner	Alex Alba: Supervisor, Laboratory Analytic
Policy Area	Lab - Hematology
Applicability	Sutter Roseville Medical Center

Determination of HemoCue Plasma/Low Hemoglobin

Principle

The HemoCue Plasma/Low Hb System is used for the quantitative determination of low levels of hemoglobin in plasma specimens, using a specially designed analyzer, the HemoCue® Plasma/Low Hb Photometer and specially designed microcuvettes, the HemoCue Plasma/Low Hb Microcuvettes.

The hemoglobin concentration is determined as azidemethemoglobin utilizing a microcuvette with a dry reagent system and a dual wavelength analyzer. When present, the membranes of erythrocytes are disintegrated by sodium deoxycholate, releasing hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin, which then combines with sodium azide to form azidemethemoglobin. Measurements are taken at 570nm and at 880nm; the latter to correct for turbidity

Policy

- This is a moderately complex test and is only to be performed by trained CLS and/or MLT in the clinical laboratory.
- Testing is to be performed upon receipt on all shifts.
- Test Code: **PLHGB** *(Hemoglobin, Plasma)*

Specimen Requirements and Stability

- Blood sample is collected in Lithium Heparin blood collection tube with gel
- Blood sample is centrifuged to obtain plasma which is used for testing
- Storage and Stability
    - Sample is stable for 24 hrs at 2-8°C

    - If refrigerated, allow to sample to reach room temp prior to testing
- Visibly turbid samples should be filtered preferably with filter having a pore size of 0.2 um

Specimen Rejection

- Use of blood collection tube other than lithium heparin
- Use of sample type other than plasma
- Unrefrigerated sample greater than 24 hrs since collection

Equipment and Supplies

- Hemocue Plasma/Low Hgb Photometer
- HemoCue Plasma Low/Hgb Microcuvettes- stored at room temperature
- Lint free tissue
- Parafilm
- Disposable transfer pipettes
- Filter with pore size of 0.2 um (*if applicable*)
- Cotton swab

Start Up Procedure

- Connect AC power adapter
- Turn the photometer on using the switch in the back
- Pull out the cuvette holder to the loading position. This will be noted by a distinct stop
- After about 15 seconds the display screen will show "READY" with three flashing dashes
- The analyzer is now ready to perform a measurement

Shut Down Procedure

- Turn the photometer off using the switch in the back
- Disconnect AC power adapter

Calibration

- No calibration required
- Instrument is manufacturer calibrated

Quality Control Materials

- Eurotrol Plasma/Low Hgb control levels 1,2, and 3 run frequency:
    - Every 8 hrs when patient testing is performed
    - Monthly

- Each new lot number or shipment of microcuvettes
- After major equipment service or troubleshooting

- Eurotrol controls are stored at 2-8°C
  - Unopened vials are stable until expiration date on outer kit box
  - Opened vials are stable for 1 month when properly capped

Running Quality Control

Step	Action
1	Allow controls to sit at room temperature for 15 minutes before use.
2	Gently mix control vials 8-10 times before sampling.
3	Open a vial of HemoCue Plasma/Low Hb Microcuvettes, removing only the number of cuvettes for immediate use. Recap the vial after use.
4	Using one level of control at a time, dispense a drop of control onto a small piece of parafilm.
5	• Introduce the tip of the cuvette into the middle of the drop of control and fill completely with one continuous motion. Do not refill a partially filled cuvette. • Do not hold the cuvette by the "filling end". This could result in contamination of the optical eye.
6	Wipe off the outside of the cuvette with a clean, lint free tissue, taking care not to touch the open end of the cuvette.
7	Visually inspect the cuvette for air bubbles in the optical eye. If bubbles are present in the optical eye, discard the cuvette and repeat the process.
8	On the Hemocue instrument, pull the cuvette holder out to the loading position. Place the filled cuvette into the cuvette holder and gently slide into the photometer within one minute after filling. The display screen will show "MEASURING" and fixed dashes.
9	The result will be displayed on the screen within one minute.
10	Document QC results on Form C: HemoCue QC Log then enter results manually in the LIS
11	• Pull the cuvette holder out to the loading position, remove the cuvette and discard it into an appropriate biohazard container • Do not reuse the cuvette for repeat testing

Recording and Reviewing Quality Control Results

- Quality control results are reviewed and entered manually into the LIS using function MEM and the following worksheet and QC codes:
  - Worksheet is RVHM

- C-HGB1 - Level 1 control
- C-HGB2 - Level 2 control
- C-HGB3 - Level 3 control

- If the controls are within acceptable limits then continue to patient testing
- If any of the controls are outside of acceptable limit then rerun the affected control
  - Repeat same control vial or new control vial if necessary using new cuvette
  - Document all corrective action in the LIS
- If unable to resolve, notify the supervisor and / or contact technical support. Do **not** perform patient testing if QC is not acceptable.

Patient Testing Procedure

1 Ensure patient sample is acceptable:
- Properly labeled blood sample collected in lithium heparin blood tube with gel
- Sample is centrifuged to separate plasma
- Sample brought to room temperature

2 Using a transfer pipette, carefully dispense one drop of patient's plasma onto a piece of parafilm.

3
- Introduce the tip of the cuvette into the middle of the drop of control and fill completely with one continuous motion. Do not refill a partially filled cuvette.
- Do not hold the cuvette by the "filling end". This could result in contamination of the optical eye.

4 Wipe off the outside of the cuvette with a clean, lint free tissue, taking care not to touch the open end of the cuvette.

5 Visually inspect the cuvette for air bubbles in the optical eye. If bubbles are present in the optical eye, discard the cuvette and repeat the process.

6 On the Hemocue instrument, pull the cuvette holder out to the loading position. Place the filled cuvette into the cuvette holder and gently slide into the photometer within one minute after filling. The display screen will show "MEASURING" and fixed dashes.

7 The result will be displayed on the screen within one minute.

8 Record results on Form A: HemoCue Plasma/Low Hgb Patient Result Log.

9
- Pull the cuvette holder out to the loading position, remove the cuvette and discard it into an appropriate biohazard container
- Do not reuse the cuvette for repeat testing

Reporting Patient Results

- Patient test results are manually reported in the LIS using function MEM
    - Order code is **PLHGB**
    - Worksheet is **RVHM**

Reference Range

- <30 mg/dl for all ages ages and gender

Technical Limit

- 30 - 3000 mg/dl

Critical Value

- None

Maintenance

- Cuvette holder is removed and cleaned after each day's use
    - Alcohol pad is used to clean the holder
    - Make sure that the cuvette holder is completely dry before reinserting into the instrument
    - Make sure that the cuvette holder is locked into place by the small catch
- Instrument exterior is cleaned monthly with an alcohol pad
- Optronic unit is cleaned as needed (refer to ops manual for error messages)
    - Turn the photometer off using the switch in the back
    - Pull the cuvette holder out to it's loading position
    - Use a pointed object to depress the small catch positioned in the upper right hand corner of the cuvette holder
    - While depressing the small catch, pull the cuvette holder in the direction in which the handle of the cuvette holder is pointing
    - Using a cotton swab moistened with alcohol, push the cotton swab into the opening of the cuvette holder. Pull out and push in 5-10 times. If swab is dirty, repeat with new swab until swab comes out clean
    - Wait 15 minutes then replace the cuvette holder and turn on the photometer using the switch in the back of the instrument
- Record the maintenance task performed on Form B: HemoCue Maintenance Log

Procedural Notes and Limitations

- HemoCue (A) will be the primary instrument to be used for patient testing and Hemocue(B) will be the back up instrument.
- Air bubbles in the optical eye of the microcuvette may cause false results. If air bubbles are present, discard the cuvette and proceed with a new cuvette.
- Contamination of microcuvette optical eye by holding filling end of cuvette or contamination with sample material
- Samples that are visibly turbid should be filtered using a filter with a pore size of 0.2µm.
- If "HHH" is displayed, the result exceeds the measuring range of the system.

Supporting Documents

- Form A: HemoCue Plasma/Low Hgb Patient Result Log
- Form B: HemoCue Plasma/Low Hgb Maintenance Log
- Form C: HemoCue Plasma/Low Hgb QC Log

References

- HemoCue Plasma/Low Hb System Operating Manual
- HemoCue Plasma/Low Hb System Test Method Validation Documents

All Revision Dates

3/27/2023

Attachments

Form A: HemoCue Plasma/Low Hgb Patient Result Log

Form B: HemoCue Maintenance Log

Form C: HemoCue QC Log

Approval Signatures

Step Description	Approver	Date

Medical Director	Lindsey Westerbeck: Executive, Lab Services	3/27/2023
Laboratory Director	Lindsey Westerbeck: Director, Lab Services	3/23/2023

Sutter Roseville Medical Center
Laboratory Services

Effective Date: 3/28/2023

FORM A: HEMOCUE PLASMA/LOW HGB PATIENT RESULT LOG

	Lot Number	Expiration
HemoCue Microcuvettes		

Worksheet: RVHM

Date	Patient Information	Plasma/Low Hgb Result	CLS/MLT Initials	Results Reviewed?
	Name: MRN: Accession #:			☐ Yes ☐ No
	Name: MRN: Accession #:			☐ Yes ☐ No
	Name: MRN: Accession #:			☐ Yes ☐ No
	Name: MRN: Accession #:			☐ Yes ☐ No
	Name: MRN: Accession #:			☐ Yes ☐ No
	Name: MRN: Accession #:			☐ Yes ☐ No

FORM B: HEMOCUE PLASMA/LOW HGB MAINTENANCE LOG

SERIAL #__2213303011___HemoCue (B) _____ **MONTH / YEAR _____**

TASK	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Maintenance (after use for patient testing)																															
Clean microcuvette holder																															
Monthly Maintenance																															
Clean instrument exterior																															
As needed Maintenance																															
Clean optronic unit																															
Initials																															

CORRECTIVE ACTION		
Date/Time/Initials	**Problem**	**Corrective Action**

Reviewed By / Date :_____

"Blank Spaces Represent Not Applicable"

Form C: HemoCue (A) Quality Control Log SN 2213303017

**QC is to be run every 8 hrs when there is a patient run, with each new lot or shipment of cuvettes, in addition to monthly. Also to be performed after a major service event, for troubleshooting.*

Microcuvettes	Lot Number	Expiration Date	Date Opened

Date	Patient Run	Monthly	New Lot or Shipment	Other	QC Level 1		QC Level 2		QC Level 3		QC OK?	Initials	Reviewed By / Date
	**Check all that apply*												
					Lot/Exp Date: QC-1 Range:	Result	Lot/Exp Date: QC-2 Range:	Result	Lot/Exp Date: QC-3 Range:	Result	Y / N		
					Lot/Exp Date: QC-1 Range:	Result	Lot/Exp Date: QC-2 Range:	Result	Lot/Exp Date: QC-3 Range:	Result	Y / N		
					Lot/Exp Date: QC-1 Range:	Result	Lot/Exp Date: QC-2 Range:	Result	Lot/Exp Date: QC-3 Range:	Result	Y / N		
					Lot/Exp Date: QC-1 Range:	Result	Lot/Exp Date: QC-2 Range:	Result	Lot/Exp Date: QC-3 Range:	Result	Y / N		
					Lot/Exp Date: QC-1 Range:	Result	Lot/Exp Date: QC-2 Range:	Result	Lot/Exp Date: QC-3 Range:	Result	Y / N		
					Lot/Exp Date: QC-1 Range:	Result	Lot/Exp Date: QC-2 Range:	Result	Lot/Exp Date: QC-3 Range:	Result	Y / N		
					Lot/Exp Date: QC-1 Range:	Result	Lot/Exp Date: QC-2 Range:	Result	Lot/Exp Date: QC-3 Range:	Result	Y / N		