

GEM OPL

Oxygenation Portable Laboratory Moderately Complex Method

Principle

The GEM OPL uses multiple wavelengths (7) to obtain accurate measurements of (O₂Hb, HHb, MetHb, and COHb), oxyhemoglobin, de-oxyhemoglobin, methemoglobin, and carboxyhemoglobin respectively. Conventional whole-blood oximeters are unable to measure the total hemoglobin concentration accurately because whole blood does not really obey Beer's Law. Whole blood does not simply absorb light; the red blood cells also scatter the light. The GEM OPL uses proprietary optics and mathematical algorithms to obtain accurate measurements of total hemoglobin concentration and percent Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin.

Clinical Significance

Hemoglobin

Hemoglobin , the main component of the red blood cells is a conjugated protein that serves to transport oxygen from the lungs, where the oxygen tension is high, to the tissues, where it is low. A molecule of hemoglobin consist of two pairs of polypeptide chains(globin) and four prosthetic heme groups containing one atom of ferrous ion. Located near the surface of the molecule , the heme reversibly combines with one molecule of oxygen.

Carboxyhemoglobin

Carboxyhemoglobin is formed when carbon monoxide combines with hemoglobin , which impairs oxygen transport in the blood through two (2) mechanisms. **First**, the affinity of hemoglobin is over 200 times greater for carbon monoxide than it is for oxygen. **Second**, the exposure to even low concentrations of CO can reversibly inactivate a significant percentage of the oxygen carrying capacity of blood.

Methemoglobin

Methemoglobin is hemoglobin with the Iron atom oxidized to the Ferric state and is incapable of binding oxygen. Normally, about 99% of hemoglobin is in the reduced state and 1% is oxidized. Erythrocytes contain methemoglobin reductase which facilitates the reduction of methemoglobin by NADH under normal conditions. Congenital deficiency of hemoglobin may result in methemoglobinemia. This condition is characterized by cyanosis. At levels as low as 1.5% venous blood becomes chocolate brown in color. Methylene blue

accelerates the reduction of ferric iron and can be given to treat methemoglobinemia.

Sample Requirement

LIS Order Codes:	Carboxyhemoglobin 15060 Methemoglobin 15230
Patient preparation:	Not applicable.
Specimen Required	7 ml green top vacutainer or 5 ml heparinized syringe.
Storage/Stability	3 days at 2-8 °C, best if tested immediately.

Collection sources of Errors

1. When drawing blood samples with a syringe from a saline filled catheter, withdraw the saline first and make sure that only whole blood is sampled.
2. Citrate is known to alter the pH of the blood and cause errors in spectrophotometric measurements. Similarly, fluoride, oxalate, and EDTA should not be used.
3. Excessive volumes of anticoagulant or saline may oxygenate the sample or cause dilution errors.

Sample Preparation

1. Roll the tightly sealed syringe between your palms to keep the red blood cells and plasma well mixed. Poorly mixed samples or those containing clots may cause inaccurate results.
2. When handling cuvettes, hold them only by their black caps.
3. To avoid warming the cuvette, do not pick it up until you are ready to fill it and analyze the sample.
4. Always fill cuvette prior to inserting it into the instrument.

Preparation Sources of Errors

1. Always store cuvettes in the sealed bag with a desiccant pouch or erroneous results may occur. Check the desiccant prior to using cuvettes to ensure that the color indicator has not changed from blue to pink. If the color indicator has changed, do not use cuvettes until a new desiccant pouch can be added to the bag. Prior to use, verify indicator is blue.
2. When filling a cuvette, do not use excessive pressure or cause the vent patch to bulge outward. If the vent patch protrudes, discard the cuvette. Never insert a cuvette with a protruding vent patch into the instrument.
3. If the sample in the cuvette is poorly mixed or contains clots, discard the cuvette to prevent erroneous results.

Instrumentation and Materials

The GEM OPL System consists of the following components:

1. GEM OPL
2. Single use cuvette
3. Optical QC filters (orange and yellow)
4. AC adapter
5. Temperature probe

Calibration

1. Selecting the Calibration option from the Main Menu displays the following Calibration menu:
 - a. GEM Code
 - b. Cuvette Lot Number
 - c. Hufner's # 1.30-1.39

GEM Code

Each package of cuvettes is labeled with a GEM Code used by the GEM OPL to obtain correct measurements. The currently defined GEM Code is displayed on the Ready screen for visual verification each time a sample is analyzed. Selecting the GEM Code option from the Calibration Menu displays the GEM Code currently defined. Press Cancel or OK to leave the GEM Code as currently displayed, or change the current value. When a new GEM code is entered, GEM OPL automatically compares it with an internal table of acceptable codes. After entering a four digit numeric GEM Code, the operator must confirm the entry in a subsequent display. Upon acceptance, the GEM OPL verifies that the entry is a valid GEM Code and presents an error message if the GEM Code entered does not match one of those defined by the manufacturer.

Cuvette Lot Number

Selecting the Cuvette Lot Number option from the Calibration Menu displays the cuvette lot number currently defined. Press Cancel or OK to leave the current one or change the current value. The lot number can also be changed following completion of analysis during collection of sample information.

Hufner's Number

Hufner's Number , the constant (k) in the following equation , is used to compute the oxygen content (O2Ct) of each sample.

$$\text{O2Ct} = k \times \text{tHB} \times \% \text{O2HB}/100$$

Selecting The Hufner's Number option from the Calibration Menu displays the currently defined value of Hufner's Number. Press **Cancel** or **OK** to enter a new value or leave current value. To eliminate keying errors, the GEM OPL allows entry of only the final digit. Entry of 0 to 9 redisplay the entry confirmation.

GEM OPL Operating Ranges

Total Hemoglobin	4 – 25 g/dL
Oxyhemoglobin	0 – 100 %
Carboxyhemoglobin	0 – 75 %
Methemoglobin	0 – 85 %

Quality Control

Two types of controls are available for use on the GEM OPL: Optical QC filters (yellow and Orange) and Liquid control materials.

A. Optical QC filters

Each GEM OPL is equipped with cuvette-shaped yellow and orange optical QC filters that can be inserted into the instrument to simulate a blood sample of known composition. Each filter has a serial number that matches the serial number of the GEM OPL with which it is used.

1. Frequency of Optical Filters QC

- a. Once each day of patient testing
- b. When an analyzer is brought from hot to cold temperature or vice versa
- c. Whenever the performance of the analyzer requires verification

2. Optical QC Procedure

- a. Confirm that the filters have the same serial number as the GEM OPL.
- b. Wait until the READY message appears on the display
- c. Remove any debris from the surface of the optical filters by wiping them with dry gauze prior to inserting them into the GEM OPL.
- d. Insert the filter into the cuvette slot and enter the sample information at the prompt.
- e. Verify that each of the results is within the established range for the filter. Proceed with the other filter if each value is within range.
- f. **Discontinue using** the instrument for clinical purposes if any of the values are outside of the specified range and refer to Troubleshooting section of the Operator's Manual or contact Technical Support.

3. Optical QC Ranges

Analyte	Yellow Filter	Orange Filter
THB (g/dl)	7.8 to 8.2	16.7 to 17.3
%O ₂ Hb	93.7 to 96.3	37.8 to 40.2
%COHb	0.6 to 2.4	20.0 to 23.0
%MetHb	-0.4 to 2.4	0.2 to 1.8

B. Liquid QC

IL Multi-4 Co-Oximeter Controls; Levels 1, 2, and 3.

Each ampule contains purified human hemoglobin, stabilizers and biocide in a physiologically buffered matrix. Each ampule contains 1.7 ml of solution.

WARNING: HUMAN SOURCE MATERIAL.

This product contains human source material that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen, and anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

1. Storage and Stability of Liquid QC

- Store Multi-4 Co-Oximeter Controls at 2 - 8°C. Each lot of QC has the expiration date stamped on the box and the ampule label.
- Multi-4 Co-Oximeter Controls should be reddish in color when received and remain so until the expiration date. Change of color to brown and/or inability to achieve listed values is an indication of deterioration.

2. Frequency of Running Liquid QC: Weekly or with each new lot or shipment of cuvettes

3. Liquid QC Handling

- Hold the ampule by the top above the break line and shake with gentle tapping. Restore all liquid to the bottom of the ampule with gentle tapping.
- Use appropriate ampule openers to protect fingers while opening. Carefully snap open the ampule.
- Sample contents immediately after opening.
- Analyze immediately following removal from the refrigerator. Do not hold ampule in the palm of the hand for shaking.
- Analyze as per following procedure.

4. Liquid QC Ranges

Reference ranges for each lot of Multi-4 Co-Oximeter Controls are printed on the package insert. The stated reference range on the insert serves as a guide for the user. IL recommends that each laboratory establish its own mean value, which should fall within the specified range.

Sample Analysis Procedure

1. Sample analysis does not require use of the numeric keypad until after the sample analysis is complete and prior to display of results. After analysis is complete, sample identification through selection or entry of numeric values may be done.
2. KeyPad
 - a. **Enter/On** accepts selections. When the screen presents a menu, press the appropriate number key to make your selection followed by the Enter/On key to accept your selection and proceed to the next screen.
 - b. **Backspace** erases the character immediately to the left of the cursor. This key should be used when changing an operator –entered numeric string of characters.
 - c. **Cancel** returns to the previous menu
 - d. **Yes/+** moves ahead one record or setting in select functions
 - e. **No/-** moves back one record or setting in select functions
 - f. **Print** prints a hard copy of the results to the attached external printer.
 - g. **Main Menu** provides access to a series of menus or options to configure Calibration, specify Printing option, view Stored Data, or Power Down the GEM OPL.
 - h. **Computer** provides access to a series of menus or options to enable Data Management features and configure Device settings.

Patient Sample/ QC Testing

Sample Type: Whole Blood or Liquid QC

1. To facilitate testing of samples collected in containers other than syringes, take an aliquot of the sample using an appropriate size of syringe.
2. Sample Volume: 50 ul to fill the cuvette
3. Analysis time : 10 seconds
4. Verify that the GEM OPL screen says READY
5. Expel one drop of sample from syringe and connect sample filled, plastic syringe to a new disposable cuvette.

6. Hold the cuvette downward at 45 degree angle and inject sample into cuvette until sample reaches the vent patch at the opposite end. Leave the syringe attached to the cuvette. (Caution : Never force sample into cuvette. If cuvette does not fill easily, discard it and use another one.
7. Confirm that the light path at the widest portion of the sample chamber is free of debris or air bubbles. Ignore bubbles outside of the lightpath.
8. Remove any sample on cuvette's exterior surfaces before inserting cuvette into the GEM OPL. Do not overpressure the cuvette or cause the vent patch to bulge outward.
9. **Holding the cuvette by the black cap, rotate it so the textured blue side of the vent patch will be on the left when the cuvette is fully inserted into the slot of the instrument panel. Insert cuvette within 10 seconds of filling it.**
10. Observe the LCD display. At the screen prompt, remove the cuvette and select the sample type.
11. After the sample information is entered, the results will be displayed.
12. After the results appear, the data will stay on the display until the Enter/On key is pressed. If SO2 results are enabled, a second screen displaying **SO2, O2Ct, and O2Cap** is accessible by pressing the **Enter/On key**. Pressing the **Enter/On key a second time** will return to the **Ready Screen**
13. To analyze the next sample , obtain a fresh cuvette from the bag and repeat the previous steps.

Result Reporting

Manually enter values into LIS Results Entry by accession number.
Document critical values according to laboratory policy.

	Reference Range	Age
Carboxyhemoglobin(CO)	0.0 – 5 %	0 – 150 yrs
Methemoglobin	0.0 – 1.5 %	0 – 150 yrs
Total Hemoglobin	13.7 – 17.3	18 – 150 yrs (M)
	12.0 – 15.5	12 – 150 yrs (F)

Critical Values

Carboxyhemoglobin ≥ 15

Results Retrieval

1. Select the Stored Data option from the Main Menu
2. Upon selection of this function, the GEM OPL displays the currently available range of sample numbers.
3. The highest sample number is most recent successful sample analysis.
4. Enter the desired sample number.
5. The results will be displayed.
6. Press cancel to return to "ready state".

Procedural Notes:

The OPL may be used as a back-up for Oxygen Saturation testing typically performed on point of care analyzers. When used for this purpose:

1. Order LIS Test Code 15274 for each specimen.
2. Perform testing as described in this procedure.
3. Results need to be corrected prior to reporting:
 - a. $O_2 \text{ Saturation, Arterial (\%)} = O_2Hb - (COHb + MetHb)$
 - b. Manual calculations should be verified by second tech to confirm prior to reporting.
 - c. Automated calculation can be performed in Chemistry Calculations Spreadsheet, found on intranet. These do not require review prior to release.
4. In LIS Manual Result Entry record results
 - a. O2SATART = corrected result from 3.a above.
 - b. SOURCEO2 = specimen source as documented on each sample.

References

1. GEM *OPL* Operator's Manual; Instrumentation Laboratory; PN 6320480230 Rev.02 December 2003

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Medical Director Approval: Donald Frederick PH.D.

Change of Medical Director: Robert Benirschke, PhD September 21, 2012
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REVISION HISTORY			
Rev	Description of Change	Author	Effective Date
0.1	Added LIS order codes, changed LIS reporting, removed GEM reference in result lookup.	T. Mikolajczyk	7/19/2011
0.2	Added Procedural Notes to include handling back-up POC O2 Sat testing. Delineates test code, calculation, and reporting of results.	T King	12/18/2012

Reviewed

Coordinator	Date	Medical Director	Date
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