HealthPartners/GHI

Co-oximetry Gem-OPL Point of Care Procedure **(Oxygenation Portable Laboratory – HSC Lung & Sleep Health Only)**	**Attachments** ☐ Yes ☒ No
Key words Co-oximeter, blood gases, Co-oximetry, CO, Carbon Monoxide	**Number** **GHP-PC-CLINIC LAB-PROCEDURES-Co-Oximetry GEMOPL v. 05-2010**
Category Provision of Care	**Effective Date** **October 2005**
Manual Clinic Laboratory Procedure Manual	**Last Review Date** **February 2013**
Issued By Laboratory Administration	**Next Review Date** **February 2014**
Applicable Health Specialty Center Staff	**Origination Date** **October 2005**
Level of Complexity Moderate	**Retired Date**
Review Responsibility Laboratory Technical Consultants	**Contact** Laboratory Technical Consultants
APPROVAL(S) Laboratory Medical Director	**Approved Date** **October 2005**

GEM OPL CoOximeter Procedure

I. PURPOSE/PRINCIPLE

To provide direction for performing O_2, CO, and met-hemoglobin tests using the GEM OPL instrument

Whole blood samples are measured for total hemoglobin concentration and the relative concentrations of oxy-, carboxy-, and methemoglobin. The GEM OPL illuminates the sample with multiple wavelengths, records the optical absorbance of the sample at each wavelength, and computes the results.

II. POLICY

Laboratory Staff will follow the approved techniques outlined in this procedure.

Specimen:

Whole blood samples are drawn in a heparinized syringe and sodium or lithium heparinized vacutainer tubes are acceptable.

Citrate, fluoride, oxalate and EDTA tubes are NOT acceptable.

Reagents/ Materials:

- Disposable cuvettes- cuvettes are obtained from Instrument Laboratories. Store cuvettes in the sealed bag with a desiccant pouch at room temperature. The desiccant pouch has a color indicator that should be blue. If the color indicator has changed to pink, do not use the cuvettes until a new desiccant pouch can be added to the bag. Prior to use, verify indicator is blue.
- There is no expiration for cuvettes properly stored.
- The temperature probe located on the rear panel of the instrument should be kept by the cuvette bag, which is currently in use.

Quality Control:

1. OPTICAL FILTERS: Optical filters are used to determine whether the optics have been contaminated and to verify that the calibration has not changed. There are two optical filters-yellow and orange. Each filter has a serial number that matches the serial number of the GEM OPL with which it is used. Both filters are to be run weekly and once each day of patient testing.

   To Perform:
   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.
   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.

2. LIQUID QC. Liquid QC serves as another means to verify that the GEM OPL system is functioning properly. Controls are the IL Multi-4 CO_Oximeter controls levels 1,2, and 3. They are obtained from Instrument Laboratories. Store at 2-8C. Expiration date is stamped on each vial. If criteria for Equivalent Quality Control has been met, Liquid Control should be performed weekly. If EQC has not been met, run 3 levels of control each day of testing. Document QC on the Quality Control Log and send to the lab at the end of the month.

   - The tech performing Quality Control must compare each level of QC results with the corresponding QC ranges to verify they are in range.
   - The QC ranges are found on the QC package insert.
   - The correct control lot number information, Cuvette lot number information, ranges, dates, and tech initials must be recorded on the logsheet.
   - If the results are out of range, repeat the control one time to see if it comes in range. If not, discontinue testing and notify the lab for further direction.

   To Perform:
   a. Hold the ampule by the top above the break line and shake the ampule with gentle tapping. Restore all liquid to the bottom of the ampule.
   b. Snap open the ampule and fill cuvette with control. Insert the cuvette into the instrument. Note: Analyze immediately following removal from the refrigerator.
   c. Verify that results are with in the established ranges.

Equivalent Quality Control:

GEM-OPL is a testing system that qualifies for Equivalent Quality Control since there is an internal quality control mechanism which monitors all sources of error..

This procedure consists of performing both internal QC and three levels of external QC for 10 consecutive testing days. If all results are acceptable for both internal and external QC the laboratory may then perform and document internal QC daily and perform and document external QC weekly and with each new lot number.

If any of the following occurs, the lab must stop using the equivalent QC protocol until corrective actions have been completed and documented.

- Either internal or external QC failures that are not resolved by repeating the control one time
- PT failure
- Any problems identified with this testing as a result of analytic Quality assessment activities.

The laboratory must revert to performing three levels of external QC every day of patient testing while troubleshooting and solving the problem.
Another Equivalent Quality Control study must be performed before resuming Equivalent Quality Control Procedures.

Calibration:
The initial calibration is set at the factory. Recalibration is required only if the optical filters do not meet the established specifications.

Calibration Verification:
Calibration Verification is performed every 6 months using a purchased assayed 5 level set of Calibration Verification Controls. Calibration Verification is also performed after instrument service.

There are 5 levels of samples (3 samples for each level) with known values and are tested in the same manner as patients. The results obtained are plotted on a graph, compared to the known values, and must be within established acceptable limits. If the calibration is stable, the recovered value should match the expected value. If not, troubleshooting and correcting action are needed.

III. PROCEDURE

Verify that the GEM OPL is ready. The display will read: READY insert cuvette. Verify that the GEM Code is correct for the cuvette bag in use. If not it must be changed. To change the GEM Code, press MAIN MENU on the keypad. Select the CALIBRATION option from the main menu. Select 1. GEM Code. This will display the current code. Change the code to match the cuvette bag.

1. Roll the syringe between your palms to keep the cells and plasma well mixed.
2. Expel one drop of sample from the syringe and connect the syringe to a disposable cuvette.
3. Hold the cuvette at a 45 angle and inject sample into cuvette until sample reaches the vent patch at the opposite end.
4. Confirm that the light path at the widest portion of the sample chamhber is free of debris or air bubbles. Ignore bubbles outside of the light path.
5. Remove any sample on the cuvettes exterior surface before inserting into the GEM OPL.
6. Holding the cuvette by the black cap, rotate it so the textured blue side of the vent patch will be on the left side when inserted. Insert the cuvette within 10 seconds of filling it.
7. Follow the screen prompt to enter sample information.
8. After the results appear, hit PRINT to get a hard copy. The data will stay on the display until the Enter/On key is pressed.

Linearity:

tHB 5-21 g/dL
O2Hb 0-100%

Reference Range
tHB 12.0-18.0 g/dl

Reporting Results:

1. Record Results on Manual Worksheet (Check the column with the matching results)
2. For Computer entry use Function: MEM
3. Worksheet: BG2HS
4. Refer to page 5 for complete result entry instructions.

Pulmonary:
Either hand write or use a computer generated label to supply the following information to the lab with each test request:

- Patient Name
- Birthdate
- Medical Record
- Encounter Number
- Date & Time of Testing
- Diagnosis Code
- Ordering Provider
- Tech Number
- Test Name and Test Result

At the end of the day, fax the results to the lab at 651-254-8191. The lab will enter the patient information and their results into Misys.

Procedure Notes:

- When handling cuvettes, hold them only by their black caps.
- Always fill cuvette prior to inserting it into the instrument
- 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. To avoid contaminating the optics, never insert a cuvette with a protruding vent patch into the instrument.

Troubleshooting:
If liquid controls or optical controls are out of range, see pages 37-39 of GEM OPL Instrument Manual.

Technical Service Phone Number: 1-800-678-0710.

Troubleshooting Guide:
OPTICAL FILTERS:
There are two optical filters-yellow and orange. Each filter has a serial number that matches the serial number of the GEM OPL with which it is used. Both filters are to be run once each day of patient testing.

LIQUID QC. Controls are the IL Multi-4 CO_Oximeter controls levels 1, 2, and 3. Store at 2-8C. Expiration date is stamped on each vial. Liquid Control should be run once per week and upon receiving a new shipment of cuvettes.

Troubleshooting

1. If controls are out of range, rerun controls. **Never** report any patient results when Q.C. values fall outside of the stated control ranges.
2. Liquid Control: Verify that the correct lot number is being used.
   Optical Filters: Verify that the serial number of the filter matches the serial number of the GEM OPL.
3. Liquid Control: Verify that controls are not expired and that the controls have been stored correctly.
4. Verify that the procedure was run correctly.
5. Verify that proper cuvette handling and sampling technique was used.
6. Verify that the GEM code on the box of cuvettes matches the GEM code that was entered into the instrument.
7. Rerun controls.
8. Liquid Controls: If the control values are still unacceptable, open and run new controls, if possible.
9. If Liquid Controls or optical filters remain out of control, or if you are experiencing other problems with the instrument, see pages 37-39 of the GEM OPL Instrument Manual.
10. Notify a lab technical consultant. The manufacturer may be called, if necessary. Technical Service Phone Number: 1-800-678-0710.

Reminder: According to the Internal Quality Control Policy, If expected QC values are not attained, patient results will not be reported until troubleshooting is complete.

References:

GEM OPL Manual, 2004
Regions Hospital Laboratory I-STAT Procedure, 4/1999

Author/Reviewers:

Original Author: DABergo
Most Recent Reviewer: DABergo

IV. DEFINITIONS

V. COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

VI. ATTACHMENTS

VII. OTHER RESOURCES

VIII. ENDORSEMENT

Laboratory Administration

Computer Order and Result Entry

GEM OPL Oxygenation Portable Laboratory
Order Codes: COOXB

RESULTING:

Function MEM, worksheet BG2HS

RESPONSE

Test Code	Test Name	Other Comments
THGB	Total Hgb, COOX	Enter results to 1 decimal place
FO2HB	O2 Sat, Measured	Enter results to 1 decimal place, Extra information will automatically append-normal range info.
COWB	Carbon Monoxide	Enter results to 1 decimal place. Extra information will automatically append-normal range into.
METHB	Methemoglobin	Enter results to 1 decimal place
O2CN	O2 Content	Enter results to 1 decimal place. Extra information will automatically append-normal range into.

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