CWPC_OPL_0100

GEM OPL Standard Operating Procedure

Contents

Purpose:

This document outlines policies and procedures for using the GEM OPL (Oxygenation Portable Laboratory) instrument for total hemoglobin and percentage oxyhemoglobin measurements.

Scope:

Operation and clinical use of the GEM OPL is limited to one site at BCCH. Only trained users who meet annual competency requirements are authorized to use this instrument for patient testing.

Level of Personnel: Cath Lab Medical Radiology Technologists and Registered Nurses
Testing Site: Cardiac Cath Lab, TACC BC Children's Hospital

Rationale for Testing:
Physicians may give a verbal order for oxygen saturation measurement. Reasons may include, but are not limited to

- cardiac output calculation (Fick)
- ASD, VSD, PFO studies
- verification of arterial/venous access
- respiratory compromise.

This procedure must be followed by all operators of the GEM OPL at BCCH.

Clinical personnel utilizing these results for patient management should be familiar with the policies and procedures as well.

Program Responsibility:

- The following laboratory and clinical staff have direct responsibility for the maintenance, regulatory compliance and quality of the GEM OPL POCT program at BCCH:
    - Registered Nurses in the Cardiac Cath Lab
    - Radiology Technologists in the Cardiac Cath Lab
    - Medical Laboratory Technologists in POCT Lab
    - Chemistry Laboratory Technical Coordinator and Team Lead

Definitions:

POCT: Point of Care Testing
tHb: Total Hemoglobin
O2Hb: Oxyhemoglobin
COHb: Carboxyhemoglobin
MetHb: Methemoglobin

Test Principle:

The GEM OPL gives rapid measurements of total hemoglobin concentration and the relative concentrations of O2Hb, COHb and MetHb.

Analysis is quickly accomplished by injecting 50 uL of whole blood sample into a disposable cuvette and inserting the cuvette into the instrument. The GEM OPL then illuminates the sample with multiple (7) wavelengths, records the optical absorbance of the sample at each wavelength, and computes the results. The results are displayed on the LCD display on the front panel.

The total hemoglobin concentration measured by the *Gem OPL* includes oxy-, deoxy-, met-, and carboxyhemoglobin:

$$[tHb] = [O2Hb] + [HHb] + [MetHb] + [COHb]$$

Note: tHb is displayed in units of g/dL (to convert to g/L, multiply the value displayed on the instrument by 10).

The percentage of oxyhemoglobin reported by the Gem OPL is the fractional saturation:

$$\%O2Hb = \frac{[O2Hb] \times 100}{[O2Hb] + [HHb] + [MetHb] + [COHb]}$$

Supplies:

Product	Vendor	Ordering Info	Storage (unopened)
GEM OPL Disposable Cuvettes, 100/box	Instrumentation Laboratory	Vendor # 6320480100	Room Temp, tightly sealed. If desiccant indicator is pink, the cuvettes were improperly stored. Do not use cuvettes.
Optical QC filters Yellow and Orange, G8290	Instrumentation Laboratory	Vendor # 6320480221	RT
RNA CC527 Blood Gas-Electrolyte-CO-Oximeter Controls (Levels 1, 2 and 3), 30 ampoules/box (10 of each level)	RNA Medical	PS# 00085212	Fridge 2 - 8ºC. Expiry date on storage box and ampoule.
3 mL Syringes (no additive), 200/box		PS# 00019545	
Syringe Caps, 200/box		PS# 00019532	
Blunt Fill Needle 18G, 100/box		PS# 00072447	
CaviWipes		PS# 00010444	
Blood Gas Syringes			
1 mL Syringes (no additive)			

Critical Elements:

1. Do not inject blood directly into cuvette slot.

2. Never re-use a test cuvette once it has been inserted into the analyzer.

3. Do not remove the syringe from the cuvette until testing is complete.

4. Check for blood clots from patient specimen prior to injection.

5. A delay in analysis of greater than 30 seconds may yield erroneous results.

6. Air bubbles will yield erroneous results. If any air bubbles are present in the light pathway, discard cuvette.

7. Overfilling of the testing cuvette is a common source of error. Do not insert a cuvette if vent patch is bulging outward. This action will cause blood to cover the optics window inside the instrument and affect results. Contact POCT Lab if instrument contamination is suspected.

8. Optical filters are instrument-specific and can only be used with the instrument of the same serial number.

9. Cuvettes must be stored sealed with a desiccant pouch. Do not use cuvettes if desiccant colour indicator has changed from blue to pink. Discard cuvettes if indicator is pink.

Limitations and Interferences:

1. The GEM OPL measurement ranges for %O2Hb is 0 to 100% and for tHb is 4 to 25 g/dL. Samples with results outside of these ranges should be confirmed with an alternate testing method such as a blood gas analyzer.

   NOTE:
   If out-of-range result is consistent with clinical status, take action as clinically indicated. Defer testing until clinical action completed or order simultaneous lab-drawn test.

2. The GEM OPL is not validated for %COHb and %MetHb measurements at BCCH.

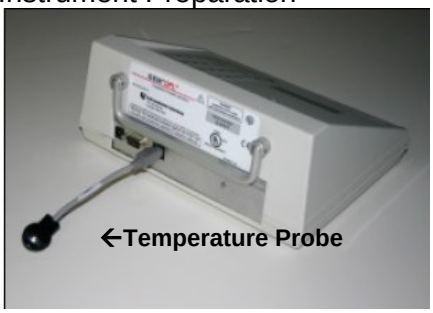
3. An incorrect tHb value will be obtained if the correct pathlength for the cuvettes in use is not entered into the GEM OPL. Optical path length is specific for each bag of cuvettes and must be set in the instrument each time a new bag of cuvettes is opened.

4. Lipemia can interfere with co-oximetry measurements.

5. Acceptable specimen types: Sodium or lithium heparinized plastic syringe. Non-additive syringes are acceptable but testing must be done immediately to avoid clot formation.
   Unacceptable specimen types: Citrate, fluoride, oxalate, and EDTA can give erroneous results.

6. Excessive volumes of anticoagulant or saline may oxygenate the sample or cause dilution errors.

Procedure A: Starting Up GEM OPL

<table>
<tr><th></th><th>Action</th><th>Related Documents
Title
Number</th></tr>
<tr><td>1.</td><td>Instrument Preparation
 

The following must be confirmed before the instrument is turned on:
1. Confirm the instrument is on a level surface, away from drafts and flammable agents.
2. The instrument is plugged in.
3. The temperature probe is attached and placed near the cuvettes.</td><td></td></tr>
<tr><td>2.</td><td>Turn on the instrument by pressing the Enter/ON key.</td><td></td></tr>
<tr><td>3.</td><td>Upon start-up, the GEM OPL will do a self-test to confirm the proper operation of its light sources.</td><td></td></tr>
<tr><td>4.</td><td>Once the warm up is complete and self-test passes, the display will show the READY screen:
- - - READY - - -
Insert Cuvette
GEM Code = 3138
Verify that the GEM code on display matches the code of the cuvette bag in use.</td><td></td></tr>
<tr><td>5.</td><td>If</td><td>Then</td></tr>
<tr><td></td><td>GEM code does not match cuvette bag code</td><td>proceed to Procedure B.</td></tr>
<tr><td></td><td>GEM code matches and READY is displayed</td><td>proceed to Procedure C.</td></tr>
</table>

Procedure B: Updating Cuvette GEM Code and Lot Number for New Lot of Cuvettes

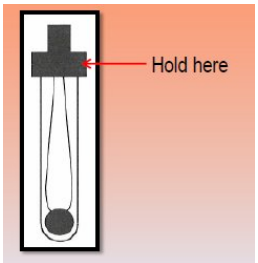
	Action	Related Documents Title Number
1.	Press **Main Menu** key.	
2.	Select **1** Calibration. Press **Enter**.	
3.	Select **1** Cuvette GEM Code. Press **Enter**.	
4.	Select **2** Enter New Value. Press **Enter**. Input the four-digit GEM code listed on the cuvette bag. Press **Enter**.	
5.	Select **2** Cuvette Lot Number. Press **Enter**.	
6.	Select **2** Enter New Value. Press **Enter**. Input the last three digits of the lot number listed on the cuvette bag. Press **Enter**.	
7.	Press **Cancel** twice to return to READY screen.	
8.	Record the cuvette lot number and date in use on the QC Record Form. Confirm GEM code has been updated on the READY screen.	CWPC_OPL_0105_GEM OPL Maintenance and Quality Control Record Form

Procedure C: Performing Optical Quality Control

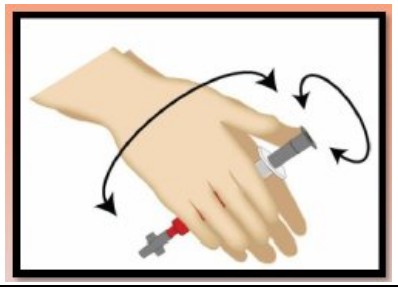
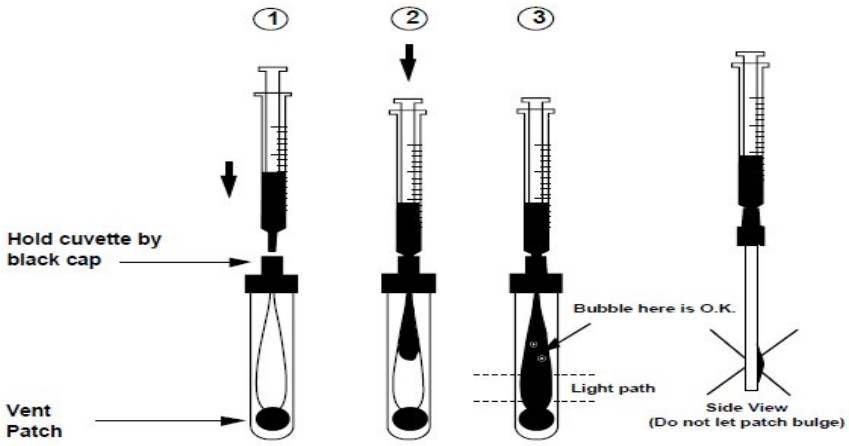
<table>
<tr><th></th><th>Action</th><th>Related Documents
Title
Number</th></tr>
<tr><td>1.</td><td>Optical QC must be run
daily prior to patient testing
when the analyzer has been moved
when there is a significant change in temperature
when the analyzer performance requires verification.</td><td></td></tr>
<tr><td>2.</td><td>Obtain the cuvette-shaped yellow and orange optical filters that are designated for the GEM OPL instrument. The filters and the GEM OPL must have the same serial number, SN G8290.</td><td></td></tr>
<tr><td>3.</td><td>Under the READY screen, insert the yellow filter into the cuvette slot with the labelled side facing left.</td><td></td></tr>
<tr><td>4.</td><td>After instrument is done analyzing,
Select 2 QC. Press Enter.
Select 2 Optical. Press Enter.
Select either 1 Yellow or 2 Orange. Press Enter.
Select 1 OK. Press Enter.</td><td></td></tr>
<tr><td>5.</td><td>Record the tHB and O2Hb results on the Quality Control Record Form.</td><td>CWPC_OPL_0105_GEM OPL Maintenance and Quality Control Record Form</td></tr>
<tr><td>6.</td><td>Remove optical filter and return it back to storage box. Do not discard. Press Cancel to return to READY screen.</td><td></td></tr>
<tr><td>7.</td><td>Repeat step 3-6 for the orange filter.</td><td></td></tr>
<tr><td>8.</td><td>Verify that the optical QC readings are within acceptable ranges:
<table>
<tr><th>Analyte</th><th>Yellow Filter</th><th>Orange Filter</th></tr>
<tr><td>tHb (g/dL)</td><td>7.8 to 8.2</td><td>16.7 to 17.3</td></tr>
<tr><td>%O2Hb</td><td>93.7 to 96.3</td><td>37.8 to 40.2</td></tr>
</table></td><td></td></tr>
<tr><td>9.</td><td>If</td><td>Then</td><td></td></tr>
<tr><td></td><td>all optical QC results are within the acceptable range</td><td>proceed to Procedure D.</td><td></td></tr>
<tr><td></td><td>any optical QC results are outside of the acceptable range</td><td>repeat testing. If QC is still out, do not use the instrument for patient testing. Notify POCT Lab.</td><td></td></tr>
</table>

Procedure D: Performing Liquid Quality Control

	Action		Related Documents Title Number
1.	Liquid QC • should be run daily prior to patient testing • is ideally run by the same operator(s) who will be performing patient testing that day • is composed of human-source donor material and must be handled with proper laboratory safety procedures using universal precautions.		
2.	**If**	**Then**	
	new QC ampoules must be used	proceed to Step 3	
	QC material to be used is already in a syringe	proceed to Step 8	
3.	Obtain one ampoule for each level of RNA QCs from the fridge in Room T4-616 (S/N T00018916).		
4.	If using a new lot of QC, the QC lot numbers must be inputted into the instrument before QC testing: a) Press **Computer**. b) Select **1** Data Management. Press **Enter**. c) Select **4** QC Lot. Press **Enter**. d) Select **1** Level 1. Press **Enter**. e) Select **1** [old 7-digit lot number]. Press **Enter**. f) Select **2** Enter New Value. Press **Enter**. g) Input the new 7-digit lot number. Press **Enter**. h) Repeat Step c to g for Level 2 and Level 3. i) Press **Cancel** twice to return to READY screen.		
5.	Hold the ampoule by the top above the break line and shake the ampoule for 10 seconds to mix. ***Note:*** *Do not hold the ampoule in the palm of the hand when shaking.*		
6.	Restore all the liquid to the bottom of the ampoule by gentle tapping.		
7.	Use an ampoule opener to carefully snap open the ampoule.		
8.	Transfer the liquid to a 3 mL syringe and cap tightly. Label syringe with date prepared. ***Note:*** *If tightly capped in the syringe, the QC samples can be used for up to one week at room temperature.*		
9.	Mix QC Level 1 syringe thoroughly by rotating through two axes – gently inverting syringe 10 times and rolling it horizontally for 10 seconds.		
10.	Uncap the syringe, discard first drop and attach a disposable cuvette to the tip of the syringe. Point the cuvette downward at 45-degree angle.		

	Action		Related Documents Title Number
11.	Press the plunger down gently and fill the cuvette until the QC sample reaches the black textured vent patch. ***Note:*** *Do not overfill. Discard if the textured vent patch bulges or if there is blood on the outside of the cuvette.*		
12.	**Leaving the syringe attached,** hold the cuvette firmly by its black cap and insert it into the cuvette slot with the textured black patch facing **left**. 		
13.	After instrument is done analyzing, • Select **2** QC. Press **Enter**. • Select **1** Liquid. Press **Enter**. • Select **1**, **2** or **3** for the corresponding QC Level. Press **Enter**. • Select **1** current QC lot number. Press **Enter**. (If the current QC lot number is not displayed, please go back to Step 4 to input current QC lot numbers.) • Confirm cuvette lot number and press **Enter** twice.		
14.	Record tHB and O2Hb results on the QC Record Form.		CWPC_OPL_0105_GEM OPL Maintenance and Quality Control Record Form
15.	Remove cuvette as soon as analysis is complete. Discard used cuvette in a biohazard container.		
16.	Repeat steps 9 to 15 for Level 2 and Level 3.		
17.	Ensure QC values are within acceptable ranges. Acceptable QC ranges are QC lot specific and must be recorded on the QC Record Form with each new lot of QC.		CWPC_OPL_0105_GEM OPL Quality Control Record Form
18.	**If**	**Then**	
	all 3 QC levels give tHb and O2Hb values within their respective acceptable ranges	proceed with patient testing.	
	any QC values are outside acceptable ranges	repeat testing. If QC is still out, do not use the instrument for patient testing. Notify POCT Lab.	

Procedure E: Analyzing Patient Samples

	Action	Related Documents Title Number
1.	Confirm READY screen is displayed. Press any button to exit Standby Mode if required.	
2.	Obtain specimen in an acceptable syringe (heparinized or non-additive) from the Cath Lab staff. ***Note:*** *If using a non-additive syringe, testing must be done* ***immediately*** *on the GEM OPL to avoid clot formation.*	
3.	Mix blood well by rolling between palms for 10 seconds immediately prior to analysis. Uncap the syringe, discard the first drop of sample and attach a disposable cuvette to the tip of the syringe. ***Note:*** *First drop should be discarded because sample in the tip of the syringe may not mix well and can lead to erroneous results.* 	
4.	Pointing the cuvette downward at a 45-degree angle, press the plunger gently and fill the cuvette until the blood reaches the vent patch. ***Note:*** *Do not overfill. Discard if the textured vent patch bulges or if there is blood on the outside of the cuvette.* 	
5.	Leave the syringe attached.	

	Action	Related Documents Title Number
6.	Confirm that the light path at the widest portion of the sample chamber is free of debris, fingerprints or air bubbles. Bubbles outside of the light path may be ignored.	
7.	Within 10 seconds of filling, hold the cuvette firmly by its black cap and insert it into the cuvette slot with the textured black patch facing **left**. ***Note:*** *A delay in analysis may lead to erroneous results.*	
8.	After instrument is done analyzing, select **1** Patient. Press **Enter**. Record values according to Cath Lab protocol. ***Note****: Results will disappear once cuvette is removed. To look up previous test results,* • *Press **Main Menu**.* • *Select **3** Stored Data. Press **Enter**.* • *Select **2** Newest Sample. Press **Enter**.* • *Press **Yes +** and **No –** to scroll through results.* • *Press Cancel three times to return to READY screen.*	
9.	Remove cuvette as soon as analysis is complete. Discard used cuvette in a biohazard container.	

Procedure F: Instrument Shutdown

	Action	Related Documents Title Number
1.	Press **Main Menu** button.	
2.	Select **4** Turn Off. Press **Enter**.	
3.	Alternatively, the GEM OPL may be turned off by pressing the **Cancel** and **Main Menu** keys simultaneously.	

Procedure G: Decontamination/Maintenance

	Action	Related Documents Title Number
1.	The GEM OPL should be decontaminated • at the end of each patient case. • before being sent to the laboratory for troubleshooting or cleaning. • after exposure to known or suspected cases of infectious diseases (e.g. MRSA). • when the analyzer looks visibly dirty or bloody.	
2.	Turn GEM OPL off.	Procedure F: Instrument Shutdown
3.	Put on gloves.	
4.	Use a CaviWipe™ to wipe down the front and sides of the instrument. ***Note:*** *Do not use excessive force, strong detergent, concentrated bleach, or abrasive cleaning solution because they can scratch or damage the surface.*	
5.	If necessary, use a cotton swab to clean the outside of the cuvette slot. Do not insert the cotton swab into the slot.	
6.	Clean the surface of the optical filters with dry gauze to prevent scratching.	
7.	Write your initials on the maintenance form to indicate maintenance has been done.	CWPC_OPL_0105 Maintenance and Quality Control Record Form

Procedure H: Annual Temperature Probe Calibration and Verification

	Action		Related Documents Title Number
1.	This procedure will be done by POCT Lab once a year.		
2.	Obtain a thermometer calibrated to National Institute for Standards in Technology (NIST) standards (accurate to at least 0.5 °C).		
3.	Using a rubber band or adhesive tape, attach the bulb end of the thermometer to the circular disk of the temperature probe.		
4.	Ensure both the probe and the thermometer are in a thermally stable environment, away from air currents.		
5.	Wait 10 minutes.		
6.	Press **Computer**. Select **3** Time, Date, Temp. Press **Enter**. Select **3** Temp & Battery. Press **Enter**.		
7.	Record the temperature displayed by the GEM OPL as well as the temperature measured by the NIST thermometer.		
8.	**If the GEM OPL's temperature reading is**	**Then**	
	within ± 3°C of the NIST thermometer	the GEM OPL temperature probe is functioning properly.	
	not within ± 3°C of the NIST thermometer	repeat step 3-8 once. If the check still fails, contact IL Technical Support.	

Troubleshooting and Technical Support:
If there are instrument problems, QC results that are not within acceptable ranges or patient results that do not correlate with the clinical picture, discontinue patient testing and notify POCT Lab staff to assist with troubleshooting. Vendor technical support may be enlisted via the laboratory. Contact information is listed below:

POCT Lab Staff
POCTLab@cw.bc.ca, Local 7521 (Mon-Fri 0700-1500)
Off-hours (limited support available): Routine Chemistry Lab, Local 7820

GEM OPL Technical Support
Vendor: Instrumentation Laboratory
GEM OPL Serial Number: G8290
Hotline: 1-800-678-0710

Back-up Instrumentation:
The GEM4000 Blood Gas Analyzer will be used if the GEM OPL is not working.

QC Policy:

Quality control materials and patient sample comparisons are performed by the same individuals performing patient testing at defined intervals to ensure proper functioning of the instrument and ongoing user competency.

Quality control materials will be ordered by Radiology. QC will be shipped to and stored in the walk-in refrigerator in the core laboratory. Laboratory staff will keep track of lot numbers and will set QC ranges for new QC lots as needed. Laboratory staff will be responsible for labelling QC boxes to indicate new lots and to identify which QC vials should be used first. POCT staff will be responsible for keeping track of inventory each month.

Cath Lab nurses/techs will retrieve QC material as needed and will keep at least 2 weeks' worth of liquid QC material in the refrigerator in the Cath lab. When retrieving QC vials, an old lot of QC should be used first. Please notify the lab when you begin to use a new lot of QC and ensure that the correct QC record form and QC acceptable ranges are being used.

At the end of each month, Cath Lab CRN will scan and email the QC Record Form to the laboratory at POCTLab@cw.bc.ca and will retain the original QC forms for documentation and as per regulatory requirements. POCT Lab staff will review this QC monthly and forward to medical staff for review as appropriate.

ALL QC results (whether they are in range or out of range) MUST be documented on the QC record forms. When QC results are out of range, patient testing must not commence, and troubleshooting, including notifying the laboratory, must occur. Users must document any corrective action that is taken when QC results fall out of range.

For the GEM OPL, the following QC procedures and testing intervals are used:

Daily, prior to patient testing:

- Optical QC using the yellow and orange filters must be tested
- All 3 levels of the liquid QC must be tested
- All results to be recorded on the QC Record Form
- All QC results must be within acceptable ranges (specific to the QC lot and outlined on the QC record form)

Every 6 months:

- CathLab staff will test one patient sample using both the GEM OPL and the GEM4000 at the same time to check instrument comparability. The form "GEM OPL Patient Comparison with GEM 4000 Form" will be completed and scanned to POCTLab@cw.bc.ca.

Proficiency Testing Policy:

Proficiency Testing (PT) refers to the analysis of samples or other materials provided by an external body for the purposes of assessing accuracy of the clinical testing process.

The GEM OPL POCT program is enrolled in the CAP PT survey which includes 3 challenges per year, each consisting of 5 samples.

The Laboratory is responsible for enrolling in and administering the PT survey. The clinical user is responsible for testing the survey samples and the costs associated with the PT survey. Upon receipt of a PT challenge, the laboratory will notify the Cath Lab CNL to arrange a time for the samples to be picked up and to communicate a time line for sample analysis and results to be returned to the lab. PT surveys must be completed within a specified timeframe to ensure results are submitted on time to allow for peer-group evaluation. This is required to maintain laboratory accreditation.

PT samples must be analyzed by the same users who perform patient testing. Analysis of PT samples can form part of annual user competency. The Cath Lab CNL or other designate should maintain documentation of whom and when PT samples were analyzed as part of competency documentation.

In order to be compliant with accreditation requirements, PT samples MUST be treated as patient specimens. This means they should be tested in the exact same manner (are as closely as possible) as patient specimens (i.e. tested only once, tested after QC has been performed and accepted, results recorded as per policy etc.).

The Laboratory will submit results to the PT provider for assessment. Once a grade is received, results will be shared with the clinical team and any deficiencies will need to be addressed in conjunction with the user group. Repeated PT failures will result in the suspension of the POCT program, as per laboratory accreditation requirements.

When PT needs to be performed, POCT Lab staff will contact the Clinical Resource Nurse of the Cardiac Cath Lab via email to arrange for the PT to be ran.

User Training, Ongoing Competency and Operator ID:

	Action	Related Documents Title Number
1.	All new users must • review this GEM OPL SOP and all related documents • go through a hands-on training session with an Educator and complete the GEM OPL Training Checklist • complete LearningHub quiz with a minimum grade of 80% • return the completed training form and checklist to POCT Lab (email: POCTLab@cw.bc.ca).	CWPC_OPL_0110 GEM OPL Training Form and Checklist

2.	All users must
	• record their operator ID on the QC record form when performing testing
	• demonstrate ongoing competency by meeting ALL the following requirements:
	  • Perform testing on a minimum of 3 levels of QC material per year
	  • Analyzing a proficiency testing sample at least once a year OR testing a patient specimen and comparing these results to those of a super-user and/or results from a blood gas analyzer at least once a year
	  • Demonstrate knowledge of instrument operation, troubleshooting and limitations.
	  • Complete the Learning Hub GEM OPL Competency Assessment Quiz (Course 18015) yearly.	

3.	All users who meet training and competency requirements will be assigned an operator ID which is to be recorded with QC and patient results. • Operator ID must not be shared and is only valid if competency requirements are met • Sharing of operator IDs will result in suspension of POCT privileges	

Program Audits:

The Point of Care Testing Lab will conduct annual audits. Please contact POCT for details of the audit. Reference procedure: CW POCT 030 Point of Care Testing Audit Procedure.

References:

Gem OPL Operator's Manual, Instrumentation Laboratory

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0	New	New document drafted by Dr. Vilte Barakauskas and updated by Diane Sze.	2020JUN08	Diane Sze	Dr. Li Wang
1.1	Minor	Non-additive syringes included as an acceptable sample type.	2020JUN25	Diane Sze	Dr. Li Wang
1.2	Minor	Validation ranges updated to measurement ranges for %O2Hb and tHb.	2020JUL02	Diane Sze	Dr. Li Wang
1.3	Minor	Added Learning Hub GEM OPL Competency Assessment Quiz to the annual ongoing competency requirements.	2021FEB01	Calvin Lee	
2.0	Major	Added action items when dealing with out-of-range results (Limitations and Interferences).	2021FEB15	Calvin Lee	Dr. Li Wang

Attention: This document is published on the ePOPS website.

Revisions made to this document require an update to the corresponding document published on ePOPS website.