CONCORD HOSPITAL
Laboratory Services
250 Pleasant Street, Concord, NH 03301
(603)227-7050 www.concordhospital.org

Title: IL GEM PREMIER 4000 Whole Blood		
ID:4894	Owner: Brent Miller	
Version: 2	Created: 03/30/2017	Reviewed: 04/19/2017
Approver: Brent Miller		Approved: 04/19/2017

TITLE: IL GEM PREMIER 4000 Whole Blood Analysis

Purpose

The GEM Premier 4000 analyzer is a portable critical care system for use by health care professionals to rapidly analyze whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, blood gases, sodium, potassium, chloride, ionized calcium, glucose, lactate, and CO-Oximetry (tHb, O2Hb, COHb, MetHb, and HHb) parameters. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, oxygen delivery capacity, and electrolyte and metabolite balance.

Scope

This procedure is intended as a guideline to all personnel assigned to the automated core section of Concord Hospital Laboratory and respiratory therapy personnel of Concord Hospital.

Procedure

PRINCIPLE OF THE TEST

System Components and Features

The GEM Premier 4000 analyzer has two primary components: the analyzer and a disposable, multi-use cartridge. These components are described in the following paragraphs.

GEM Premier 4000 Analyzer

The GEM Premier 4000 analyzer employs a unique color touch screen and a simple set of menus and buttons for user interaction. The instrument guides operators through the sampling process with simple, clear messages and prompts.

GEM Premier 4000 Cartridge (PAK)

The primary component of the GEM Premier 4000 analyzer is the GEM Premier 4000 PAK cartridge. The disposable, multi-use PAK houses all components necessary to operate the instrument once the cartridge calibration is validated. These components include the sensors, solutions, sampler, CO-Ox optical cell, and waste bag. The GEM Premier 4000 analyzer makes use of potentiometric sensors to measure pCO2, pH, Na+, K+, Cl–, and Ca++. It uses amperometric sensors to measure pO2, lactate, and glucose concentrations. CO-Oximetry measurements involve chemically lysing the whole blood sample and then utilizing a broad spectrum spectrometer to evaluate the sample at a variety of wavelengths. Automatic one-point, two-point, and low oxygen calibrations, which occur at fixed intervals, help to establish continued instrument accuracy.

The exact values of all reference solutions are read from the cartridge EEPROM. The components and processes used to manufacture the solutions in GEM Premier 4000 PAK cartridges are traceable to NIST standards whenever possible. For those analytes where NIST

materials are not available, primary analytical standards are used. Setup of the instrument consists of inserting the cartridge into the instrument. The instrument then performs a warm-up and automatically calibrates the sensors, all of which takes about 40 minutes. During warm-up, the instrument requires no user intervention. IL GEM CVP material is required to validate Intelligent Quality Management cartridges. From that point on, iQM manages the quality control process, replacing the use of external quality controls. The GEM Premier 4000 automatically notifies operators when it is time to remove the cartridge; when sample capacity has been reached, or when cartridge use life expires. The internal waste bag, which collects used blood and solutions throughout cartridge life, reduces biohazard exposure.

CLINICAL APPLICATION AND USEFULLNESS

The GEM Premier 4000 analyzer provides fast, accurate, quantitative measurements of whole blood pH, pCO2, pO2, Na+, K+, Cl–, Ca++, glucose, lactate, and CO-Oximetry.
• pH and pCO2, along with their derived parameters Base Excess, HCO3–, and TCO2, define acidbase status.
• Arterial pO2 indicates adequacy of oxygen exchange.
• Electrolytes in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes:
• Sodium is the major cation of extracellular fluid. It is critical for maintenance of water distribution and osmotic pressure in body tissues.
• Potassium is the major intracellular cation. It is critical for maintaining proper neuromuscular irritability including respiratory and myocardial function.
• Ionized calcium is critical for functions including hemostasis.
• Chloride is the major negative ion in the fluid outside the body's cells. Its main function is to maintain electrical neutrality, mostly as a counter-ion to sodium. Changes in the chloride level often accompany sodium losses and excesses.
• Glucose is the primary energy source, and its blood level is maintained within a fairly narrow range. The most common disorder affecting blood glucose levels is due to diabetes mellitus, which can cause hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose).
• CO-Oximetry evaluates the ability of the blood to carry oxygen by measuring total hemoglobin and determining the percentage of functional and dysfunctional hemoglobin species.
• Lactate is an intermediary product of carbohydrate metabolism and is derived mainly from muscle cells and erythrocytes. Severe oxygen deprivation of tissues due to shock, cardiac decompensation, hematologic disorders, and pulmonary insufficiency leads to "lactic acidosis" and is associated with a significant increase in blood lactate. Liver malfunction may also play an important role in the production of lactate.

SPECIMEN COLLECTION AND HANDLING

BIOHAZARD
All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

Specimen Type
Types of pre-defined patient samples accepted by the GEM Premier 4000 analyzer include:
• arterial
• capillary
• mixed venous
• venous
• arterial-mixed venous pairs
Acceptable fluid types (not-pre-defined, analyzed on arterial channel) are:
• pleural fluid
• pericardial fluid

Types of sampling devices accepted:
• syringe
• capillary tube
• opened ampoules

Instrumentation Laboratory recommends the use of devices coated with lyophilized lithium heparin or electrolyte-balanced heparin for use as an anticoagulant. A heparin concentration of 20 to 25 IU/mL of whole blood will prevent clot formation as long as the device is mixed thoroughly immediately after the sample is obtained. If a device is used that contains a concentration of heparin, which is less than 20 to 25 IU/mL of whole blood, it is imperative that the supplier of the device indicate that the concentration is sufficient, when mixed properly, to prevent clot formation for a period time that will allow the sample to be analyzed. Capillary specimens are collected in 170 µl Li Hep coated (100 I.U./ml) plastic capillary tubes (IL PN 24001170).
NOTE: Per IL recommendation, minimum collection volume in Lithium Heparin vacuum tubes is the halfway point (2 mLs) to prevent over-heparinization of sample. Lithium Heparin gel separator tubes are unacceptable for analysis.

Sample Volume Required for Analysis
150 µL: BG*/ Lytes**/Glu/Lactate/CO-Ox or any subset of the menu that includes CO-Ox
95 µL: BG*/ Lytes**/Glu/Lactate or any subset of the menu that does not include CO-Ox, except as noted below in the Capillary micro mode
65 µL: (Micro Mode) BG*/ Lytes**/Glu/Lactate (**Capillary Only**)
*BG = pH, pCO2, and pO2
**Lytes = sodium, potassium, ionized calcium and chloride

Sample Storage Conditions prior to Analysis
Samples have different storage condition requirements, depending on the container type:
• Plastic syringe samples/4.0 ml plastic Lithium Heparin vacuum tubes: It is recommended that plastic syringes/tubes for blood gas analysis not be iced*; they should be kept at room temperature as long as the blood is analyzed in 30 minutes or less. Oxygen and carbon dioxide

levels in blood are minimally affected at room temperature if analyzed within 30 minutes, except in the presence of an elevated leukocyte or platelet count.

*****Per CLSI document C46-A, *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*, Volume 21 Number 14, page 10, section 4.2.1.

Samples collected for special studies such as alveolar-arterial oxygen gradients (A-aDO2) or shunt studies should be analyzed within 5 minutes of collection. If time from sample collection to sample analysis for blood gas analysis will exceed 30 minutes, the use of glass syringes and storage in ice water is recommended. Samples should be placed in an ice-water slurry, with the portion of the syringe containing the sample in contact with the ice-water slurry. Samples may be stored in the ice-water slurry for up to 2 hours without significant change in pH and PCO_2; although, this will affect the K^+ values.
Specimens for ionized calcium are stable 30 minutes, or up to 2 hours if drawn on ice.
Specimens for carboxyhemoglobin are stable up to 48 hours provided the tube cap has not been disturbed.
Specimens for lactate only should be drawn without the use of a tourniquet and transported to the laboratory on ice.

• Capillary samples: Capillary samples should be analyzed within 5 minutes whenever possible. The capillary surface to blood volume ratio makes capillary samples susceptible to changes in pO2, pCO2, sO2, O2Hb, and ctO2 levels when not analyzed within 5 minutes of collection.

Sample Analysis
Prior to analysis, it is essential that the sample be thoroughly mixed. Total hemoglobin, hemoglobin derivatives, and oxygen are particularly affected when samples are not well mixed. A uniform distribution of red blood cells and plasma prior to sample aspiration is mandatory for reliable results. The sample should be rocked back and forth 5-10 times (more if sample is a 1.0 cc syringe) if drawn within 5 minutes of sampling. Rolling of the syringe between the palms is not recommended due to potential centrifugal separation of cellular components, resulting in a non-homogeneous sample. The syringe should be gently rocked for a minimum of 2 minutes immediately prior to analysis if more than 5 minutes have elapsed from sample collection. Shorter mixing intervals may be acceptable if only seconds or a few minutes have passed since collection.

Capillary tube samples should be remixed if more than 5 minutes have elapsed since collection. Nursing staff is responsible for the collection of these samples. A mixing flea (IL PN 6408400) is added at the time of collection and the flea is moved through the sample with the mixing magnet (IL PN3910100) at that time to prevent clot formation. The collector also seals both ends with capillary cap/adapters (IL PN 7071200) for transport. The following steps should be followed for analysis:

1) Just prior to analysis, the sample must be remixed using the magnet/flea combination. Move the flea back and forth while also rotating the capillary tube.
2) Select “Micro 65 µl” mode followed by “GO”. DO NOT scan the patient barcode prior to sampling.
3) Enter user code and then “Proceed without an order”.
4) The GEM sample probe will present in a horizontal orientation within a cylindrical housing.

5) Remove the end caps and mixing flea from the capillary (held horizontally) and carefully advance the leading edge of blood to one end.
6) Slide that end of the capillary tube over the probe and advance it until firmly seated against the end of the probe mount to make a tight seal.
7) Select "OK" to begin sampling, and then remove when prompted at sampling's completion.
8) The "Sample Information" screen then appears. Select "Patient ID" followed by "Key Entry". Enter the patient's medical record number. This will query the patient's demographics from the GEM Server.
9) Select "Order Number" and then scan the patient barcode. From this point onward, analysis and reporting is no different than routine testing.

REAGENTS AND MATERIALS:

The GEM Premier 4000 analyzer is comprised of two components: the instrument and a disposable, self-contained cartridge (PAK), stored at 15-25°C prior to installation. The PAK can measure pH, pCO2, pO2, Na+, K+, iCa, Cl-, Glucose, Lactate, Total Hemoglobin (tHb), and hemoglobin fractions, including Oxyhemoglobin (O2Hb), Deoxyhemoglobin (HHb), Carboxyhemoglobin (COHb) and Methemoglobin (MetHb). Hematocrit is currently not reported, and the channel is disabled. The following is an overview of the cartridge (PAK):
• All required components for sample analysis are contained in the cartridge, including sensors, optical cell for CO-Oximetry, sampler, pump tubing, distribution valve, waste container and Process Control Solutions. The cartridge components and fluidic path are schematically shown.
• The sensor card contains all of the sensors in a gas-tight chamber.
• The sensors are calibrated and monitored with four Process Control Solutions A, B, C and D. These solutions are pre-tonometered and contain known quantities of the analytes and dyes tested using NIST traceable reference standards. The solutions are sealed in gas impermeable bags with no headspace.
• Process Control Solution B is also used for rinse.
• There are two more bags in the cartridge. One is called "Reference Electrode Solution" that contains silver ion. This solution is pumped into the reference channel in the sensor card to form the Ag/Ag+ reference electrode. The second bag is called "Lysing Solution" and contains buffered surfactant. This solution is pumped into the mixing chamber of the sensor card to lyse the blood before the blood is brought into the optical cell for CO-Oximetry measurements.
• The sensor card and the optical cell reside in two thermal blocks, which maintain the temperature at 37ºC and provide electrical interface to the sensors and optical interface to the optical cell.
• The peristaltic pump moves various fluids (Sample, Process Control Solutions, Reference Electrode Solution and Lysing Solution) into the sensor card and the optical cell and eventually to the waste container.

CALIBRATION/QUALITY CONTROL:

Approximately 20 seconds after installation of a new cartridge, the analyzer will inform you that the cartridge is warming up. The clock will count down for the next 40 minutes as the cartridge warms up. During this time, the sensors will hydrate, and the analyzer will perform internal checks and calibration.

Each time a new cartridge is inserted, the GEM Premier 4000 analyzer will prompt the operator to run CVP testing. This process ensures the integrity of the new cartridge and the overall analysis system, providing a clear baseline for operation. It is necessary to perform CVP only when inserting a new cartridge. To determine how soon you will need a new cartridge, consult the **Tests/Days** button on the upper right of the Status Bar. This information enables you to schedule cartridge changes at a convenient time.
Patient results for an analyte cannot be reported until all levels of CVP pass for that analyte. Testing will require approximately 6 minutes to complete, and during this time, the analyzer will be unavailable for patient sampling. Running CVP involves testing two ampoules of testing solutions provided only by Instrumentation Laboratory. GEM CVP 1 and 2 with CO-Ox are used for all analytes except hematocrit. (Note: GEM CVP 3 and 4 are required for hematocrit. CVP 3 and 4 are not in current use, as measured hematocrit is not being reported by Concord Hospital at this time.)
NOTE: CVP 1, 2, 3, and 4 are the only external control/calibration material used for the GEM Premier 4000…all other calibration/quality control is within the analyzer cartridge and software using IQM (Intelligent Quality Management).

Intelligent Quality Management (IQM):

Once the cartridge calibration is complete, iQM monitors the status of the calibration during the cartridge use-life. Upon detecting a problem, the analyzer automatically performs corrective actions that include:
• Performing special rinse cycle in case of detecting micro-clots and verifying the cartridge function afterwards
• Permanently disabling failed sensor if its functionality cannot be recovered
• Rejecting cartridge for Process Control Solution stability failure
• Alerting the user upon detecting the presence of interfering substances in a sample
During cartridge operation, the instrument automatically and continuously performs various checks that can be categorized into four groups:
a. System checks
b. Sensor checks
c. Failure Pattern Recognition (FPR) checks
d. Process stability checks

System Checks
System checks include verifying basic functionality of the instrument and the cartridge. Examples of these checks are listed below:
• Cartridge fluidic checks, such as sample integrity, presence of Process Control Solutions and peristaltic pump functionality
• Cartridge mechanical checks, such as proper operation of distribution valve and sampler arm
• Instrument heater-block checks
• Instrument light source and spectrometer checks
• Instrument electronic checks
Any failure in the system checks will lead to an automatic corrective action. The corrective action will include verification of the failure followed by one of the following steps:
• Rejecting the cartridge in case of cartridge-related system failure

• Halting instrument operation in case of instrument-related system failure

Sensor Checks

Sensor checks address sensor functionality. The Process Control Solutions A, B, C and D are automatically brought into the sensor card at various intervals to verify sensor operation. The solution that is residing in the sensor card is measured and the drift is determined. The drift is the delta between the measured and expected value. Sensor checks are performed with the following frequencies:

• Process Control Solution (PCS) B is the primary Process Control Solution measured at a minimum of every half hour or after every sample. Furthermore, Solution B is monitored every 30 seconds while residing in the sensor card and in the optical cell between measurements.

• PCS A is measured at a minimum of every 4 hours. All sensor slope values are also measured and checked. Slope, which is an indicator of sensor sensitivity, must be within allowable limits. PCS A also contain dyes that are used for checking functionality of the optical cell and the COOximetry.

• Process Control Solution D is run as an independent check for analytes, in that this solution is not used for calibration purposes, and is measured every 12 hours. PCS D provides additional measurement for all analytes including CO-Oximetry. Reference values for analytes in PCS D are established within the first 3 days after cartridge insertion by averaging multiple measurements of PCS D. PCS D sensor check shall start once the reference values are established.

• PCS C is measured at least once every 24 hours. PCS C is primarily used for measuring lowlevel oxygen; however, PCS C is also used to provide an additional measurement of pH, pCO2 and K+ sensor functionality. PCS C is additionally used for conditioning the glucose and lactate inner membranes. Measurements of the Process Control Solutions A and B are transparent to the user and can be interrupted at any time to run a sample, except within the first 5 hours of cartridge life when these processes are uninterruptible. Measurements of the Process Control Solutions C and D are uninterruptible throughout the cartridge use-life. Process Control Solution D is performed at fixed times of day: 12 noon and 12 midnight. However, the user has the option of selecting the exact time of day for performing Process Control Solution C since this process takes longest to complete (about 10 minutes). The process of verifying the sensor operation by measuring Process Control Solutions is very similar to the process of sample measurement. The sample path and the Process Control Solution path into the sensor card are identical. After performing sensor checks, the analyzer conducts a number of actions:

• If all measured values are within allowable limits, the sensors will be calibrated and, as a result, the drifts will be set to zero.

• If any measurement or slope value is outside the allowable limits, the following corrective actions will take place:

• The parameter result in the subsequent sample report will be suppressed.

• FPR checks will be applied to determine the cause for failure as discussed in the next section.

• If the failure is not associated with any recognizable pattern, then a fresh solution will be brought into the sensor card and re-measured.

• If the failure persists in two consecutive PCS C or D measurements, or in six consecutive PCS A measurements, or in 15 consecutive PCS B measurements, then the failed parameter will be permanently disabled.

Failure Pattern Recognition (FPR) Checks

Failure Pattern Recognition (FPR) checks in the GEM Premier 4000 analyzer are of several distinct failure patterns: micro-clots, interferences and certain sensor malfunctions.

• **Micro-Clot Patterns**

Micro-clots are small blood clots or fibrin strands that adhere to a sensor and induce a change in sensor characteristics, such as sluggish response or sensitivity change. Micro-clot patterns are distinct for various sensors. Sensor-check failures (drift errors) are used to identify the presence of micro-clots. iQM automatically initiates a special rinse cycle, using Process Control Solution B, upon detecting a micro-clot pattern. When the rinse is complete, the iQM software checks for a clot pattern on the affected sensor. If a clot pattern still remains, the affected sensor is disabled. If clot pattern is not detected, the sensor status becomes green (ready for measurement). Those sensors that are disabled by clots are continually monitored and will be re-enabled once iQM confirms the removal of the clot.

• **Interference Patterns**

Several distinct interference patterns are checked:

• Positively charged lipophilic compounds like Benzalkonium Chloride that can cause false elevated readings for a few of the ion selective electrodes such as sodium and ionized calcium

• Negatively charged lipophilic compounds like Thiopental Sodium that can cause false readings for a few of the ion selective electrodes such as pCO2 and pH

• Exogenous dyes, sulfhemoglobin, cyanomethemoglobin or excessive turbidity that can interfere with CO-Oximetry measurement

In the case of interference pattern detection in a sample, the user is notified, and the operator must acknowledge the message displayed on the screen before sampling can continue.

• **Sensor Malfunction Patterns**

Beside regular sensor checks for drift and slope for all sensors, there are a few sensors that require additional pattern checks to detect certain sensor malfunctions. These sensors include pH, pCO2 and pO2. Existing sensor checks are found adequate for detecting any malfunction in the other sensors. The specific malfunctions that iQM is checking for in these sensors are very rare and very slow in progression. Therefore, the PCS C check that is performed once a day is adequate in detecting these malfunctions. In case of a sensor malfunction pattern, the affected sensor is permanently disabled by iQM.

Process Stability Check

Process stability check is a method of verifying the Process Control Solution stability throughout the cartridge use-life. This check is performed at least every 4 hours. The measured oxygen in Process Control Solutions A and D during use-life is compared to the initial measured A and D during cartridge validation by GEM CVP solutions. The delta has to be within allowable limits. The pO2 in Process Control Solutions A and D is used for the process stability check for the following reasons:

• Oxygen is considered the most sensitive parameter for detecting deterioration in the Process Control Solutions since there is no oxygen buffering in these solutions.

• The process of measuring oxygen in Process Control Solutions A and D utilizes Process Control Solutions B and C. Therefore, deterioration in any of the Process Control Solutions will be detected by this check. In the case of process stability failure, the cartridge will be rejected.

LIMITATIONS/INTERFERENCES

Limitations:

Room Air	Especially samples having a very low or high p O2 content. Similarly, pCO2 may be affected and subsequently pH and Ca++ results as well.
Metabolic Changes	Errors can occur due to metabolic changes if there is a delay in the measurement of the samples.
Elevated White Blood Cells or In Reticulocyte Counts	Samples will deteriorate more rapidly, even when kept in ice water.
Improper Mixing	Errors will be introduced for measurement of CO-Ox parameters if the sample is not properly mixed prior to measurement.
Changes to Manufacturer's Instructions or Method Verification Protocols	Results obtained may be compromised.
Improper Installation manufacturer's	The instrument must be installed per the instructions. Failure to do so invalidates any warrant, explicit or implied.
Under-Heparinized Sample	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinized.
Over-Heparinized Sample	Over-heparinized samples (sub-optimal fill of tube/syringe) may falsely lower Na+, Ca++

Interference Testing Results:
The following substances did not show noticeable interference with any channel on the GEM Premier 4000 analyzer when tested at the concentrations listed. Interference was tested on a minimum of three GEM Premier 4000 instruments.

Substance	Concentrations Tested	Maximum Expected In Vivo Concentration

acetaminophen	20 mg/dL	2 mg/dL
acetoacetate	2 mmol/L	0.3 mmol/L
ammonium	80 and 3000 µmol/L	80 µmol/L
ascorbic acid	3 mg/dL	2 mg/dL
bilirubin (total)	30 mg/dL	30 mg/dL
chlorpromazine	200 µmol/L	1.57 µmol/L
cyanomethemoglobin**	>4%	4%
dopamine	2 and 5 mg/dL	0.03 mg/dL
dobutamine	2 and 5 mg/dL	0.03 mg/dL
ethanol	100 and 350 mg/dL	100 mg/dL (toxic)
Evans Blue	10 mg/L	10 mg/L
fetal hemoglobin	85%	85%
flaxedil	2 and 5 mg/dL	1.4 mg/dL
halothane	74 and 374 µg/mL	50 µg/mL
heparin	100 IU/mL	<100 IU/mL
ß-hydroxybutyrate	2 mmol/L	2 mmol/L
ibuprofen	2 mmol/L	0.3 mmol/L
indocyanine green	10 mg/L	10 mg/L
isoniazide	2 and 5 mg/dL	2 mg/dL (toxic)
maltose	20 mg/dL	2 mg/dL (as a drug additive)
methylene blue	40 mg/L	20 mg/L
myoglobin	5 µg/mL	3 µg/mL
pralidoxime iodide	40 µg/mL	4 µg/mL
pyruvate	2 mmol/L	2 mmol/L
sulfhemoglobin**	>10%	10%
thiocyanate	5, 10 and 20 mg/dL	2.9 mg/dL
uric acid	20 mg/dL	9 mg/dL

The following substances may show noticeable interference with certain channels on the GEM Premier 4000 analyzer, causing falsely elevated results. **Note:** Hematocrit has not been validated and is not reported.

Substance	**Affected Analyte**	**Substance Concentration Producing**	**Maximum Expected In Vivo Concentration**

		Interference	
benzalkonium*	Ca^{++}	5 mg/L	10 mg/L
bromide	Cl^-	10 mmol/L	25 mmol/L
fluoride	Cl^-, lactate	500 mg/dL	1000 mg/dL (as a blood preservative)
glycolic acid	lactate	1 mmol/L	2.4 mmol/L (toxic)
Hemoglobin Based Oxygen Carriers (Hemopure®***)	hematocrit	3.2 g/dL	>6.0 g/dL
hydroxocolbalamin**	CO-Oximetry	0.5 g/L	1 g/L
hydroxyurea	glucose, lactate	0.8 mg/dL	2 mg/dL
iodide	Cl^-	3 mmol/L	3 mmol/L
oxalate	Cl^-, lactate	500 mg/dL	1000 mg/dL (as a blood preservative)
salicylate	Cl^-	4 mmol/L	2.9 mmol/L (toxic)
thiopental*	pCO_2, Ca^{++}, K^+	30 mg/L, 50 mg/L for K^+	60 mg/L (toxic)
turbidity**	CO-Oximetry	5% based on turbidity created by Intralipid®**** fat emulsion	3% intralipid is equivalent to turbidity created by a triglycerides conc. = 1500 mg/dL

*The GEM Premier 4000 analyzer with iQM employs failure pattern recognition checks. These checks include detecting the presence of positively charged lipophilic compounds (e.g., benzalkonium) and negatively lipophilic compounds (e.g., thiopental). The GEM Premier 4000 analyzer offers the operator the ability to enable flagging of patient results if interference patterns for these compounds are detected by iQM.
**CO-Oximetry interference is detected and flagged by failure pattern recognition checks.
***Hemopure® is a registered trademark of Biopure Corp.
****Intralipid® is a registered trademark of Fresenius Kabi AB.

The following substances may show noticeable interference with the glucose channel on the GEM Premier 4000 analyzer, causing falsely low results.

Substance	Affected Analyte	Substance Concentration Producing Interference	Maximum Expected In Vivo Concentration
oxalate	glucose	1000 mg/dl	1000 mg/dL

fluoride	glucose	500 mg/dl	1000 mg/dL

REPORTING RESULTS

Analytical Ranges

The measuring ranges for the GEM Premier 4000 analyzer are the ranges that the system will support in terms of actual numeric values that the system can report. The tested ranges are those ranges that were tested during functional sensitivity and linearity testing.

Measured Analyte	Units	Measured Range	Tested Range**	Resolution
pH	n/a	6.80 to 8.00	6.80 to 8.00	0.01
pCO_2	mmHg	0 to 150	6 to 125	1
pO_2	mmHg	0 to 800	5 to 690	1
Na^+	mmol/L	100 to 200	100 to 180	1
K^+	mmol/L	0.1 to 20.0	0.5 to 10.5	0.1
Ca^{++}	mmol/L	0.10 to 5.00	0.10 to 4.25	0.01
Cl^-	mmol/L	40 to 170	40 to 158	1
Glu	mg/dL	4 to 750	4 to 685	1
Lac	mmol/L	0.1 to 20.0	0.3 to 17.0	0.1
tHb	g/dL	5.0 to 23.0	5.0 to 23.0	0.1
O_2Hb	%	-10.0 to 110.0	0.0 to 98.0	0.1
COHb	%	-10.0 to 110.0	0.0 to 99.0	0.1
MetHb	%	-10.0 to 110.0	0.0 to 28.0	0.1
HHb	%	-10.0 to 110.0	0.0 to 96.0	0.1

**Tested Range is the reportable range for Concord Hospital Laboratory

User Entered Values (Temperature and Barometric Pressure)

The default temperature is 37°C. This temperature will be used to calculate pH, pCO_2 and pO_2 unless a different entry is made by the operator. The measured and corrected temperatures, if applicable, are displayed on the View Results tab and on the printout.

The default Barometric Pressure (BP) is 760 mmHg. This Barometric Pressure will be used unless a different entry is made by the operator. The GEM Premier 4000 analyzer does not need daily entry of Barometric Pressure for sample analysis, as the solutions are sealed is gas impermeable bags with no headspace. However, Barometric Pressure is used in various calculated parameter equations, alveolar oxygen partial pressure (pAO_2) for example. Therefore, if Barometric Pressure other than 760 mmHg is desired for use in the calculated parameter equations, the operator must enter it when the Enter Information tab is presented. The entered value will be displayed on the screen and shown on the printed report.

Flag Results for Interference and Micro Clots

This option is enabled in Configuration, and reporting of patient results will be delayed until the post analysis check is performed. This allows the instrument to flag analytes if interference or micro clots are detected. Auto-Accept is disabled in the analyzers, and the operator must either accept or exclude every specimen analysis performed. Specimens exhibiting either interference or micro clots should be excluded at the analyzer (and therefore not transmitted to the LIS), with analysis re-performed (without flags), or specimens recollected.

REFERENCE RANGES (Arterial):

Analyte	Reference Range (Arterial)	Critical Values
pH, arterial	7.350-7.450	<7.2 >7.6
pCO2	35.0-45.0 mmHg	<20 >65 mmHg
pO2	75.0-100.0 mmHg	<55 mmHg
TCO2 (Total CO2-est.)	23.0-32.0 mmol/L	
HCO3	21-28 mmol/L	
O2 Saturation	92.0-98.5 %	
Total Hemoglobin	12.0-18.0 g/dL	
Oxyhemoglobin (O2Hb)	94.0-97.0 %	
Carboxyhemoglobin (COHb)	0.0-1.5 %	
Methemoglobin (MetHb)	0.0-1.5 %	
Deoxyhemoblobin or reduced hemoglobin (HHB)	0.0-5.0 %	
Sodium (Na+)	137.0-146.0 mmol/L	<120 >160 mmol/L
Potassium (K+)	3.50-5.10 mmol/L	<3.0 >6.0 mmol/L
Chloride (Cl-)	96-107 mmol/L	<70 >120 mmol/L
Calcium, Ionized (Ca++)	1.13-1.32 mmol/L	
Lactate (Lac)	<1.3 mmol/L	>3.9 mmol/L
Glucose (Glu)	77-111 mg/dL	<40 >500 mg/dL

References

1. IL Gem Premier 4000 Operator's Guide, Revision 0, 10/2006
2. IL Gem Premier 4000 Reference Guide, Revision 0, 10/2006
3. IL Gem Premier 4000 Analyzer SOP, Revision 00, 1/2008
4. CH Lab Procedure "Reporting Critical Values", Rev. 7/2006
5. Preventing Pre-analytical Error Risk in Blood Gases, John J. Ancy, MA, RRT: Presented by: Christine Sears MT (ASCP) Clinical Applications Representative Critical Care, Instrumentation Laboratories, 02/09/2017

Distribution Automated Testing, Respiratory Therapy

Responsible Department/Unit Automated Testing/Technical Operations Manager

Historical Approval Initiated by Richard Adams MT(ASCP) Date: January, 2008
Adopted (date) April 8, 2008
Supercedes N/A New Procedure
Reviewed (date) 4/7/08sk
Revised (date) 7/16/10rma, 04/10/17
Approved by: Gary York MD Date: 4/8/08