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48667.263 Blood Gas, Co-oximetry, ionized Calcium, Sodium, Potassium and Hematocrit testing by GEM® 5000

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Point of Care Testing

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Blood Gas, Co-oximetry, ionized Calcium, Sodium, Potassium and Hematocrit testing by GEM ® 5000 Procedure

PURPOSE:

The **GEM® Premier 5000** test system provides quantitative measurements of pH, partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), sodium (Na^+), potassium (K^+), ionized calcium (Ca^{2+} or ICA), hematocrit (Hct), total Hemoglobin (tHb) and relative (%) measurements of Oxyhemoglobin (O_2Hb or OSAT), carboxyhemoglobin (COHb) and Methemoglobin (MetHb) on whole blood. The analyzer also calculates derived parameters including, bicarbonate $HCO3^-$, total carbon dioxide (TCO2), Base Excess and Base Deficit. The reported parameters along with the associated derived parameters aid in the diagnosis of a patient's acid/base status, oxygen delivery capacity and electrolyte and metabolite balance.

- **Blood gas measurements** help to evaluate *oxygenation* and *acid base* status.
  - **pH**, ***p*CO2**, **HCO3$^-$**, **TCO2**, **Base Excess** and **Base Deficit**, define acid-base status.
  - ***p*O2** and **O2 Content (CaO_2)** indicates oxygen.
- **CO-oximetry** evaluates the ability of the blood to carry oxygen by measuring total hemoglobin and the percentage of functional and dysfunctional hemoglobin species.
  - **Total Hemoglobin (tHb):** Total concentration of all forms of hemoglobin in blood.
  - **Oxyhemoglobin (O_2Hb)**: Fraction of ***total Hb*** that is oxygen-loaded.
  - **Carboxyhemoglobin (COHb)**: Fraction of tHb that is bound to carbon monoxide (CO).
  - **Methemoglobin (MetHb):** Fraction of tHb that has oxidized heme iron (i.e., ferric state, Fe^{3+}), which does not bind oxygen. High levels indicate methemoglobinemia.
  - **Deoxyhemoglobin (HHb):** Fraction of tHb that is not oxygen-loaded (not reported).
  - **Oxygen Saturation (sO2):** Fraction of ***available Hb*** that is oxygen-loaded.
- **Electrolytes** in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes. Imbalances can be seen in many disease states.
  - **Sodium (Na^+) [WBNA]** is the major cation of extracellular fluid. It is critical for maintenance of water distribution and osmotic pressure in body tissues.

- **Potassium (K^+) [WBK]** is the major intracellular cation. It is critical for maintaining proper neuromuscular irritability including respiratory and myocardial function.
- Calcium (Ca^{2+}) is essential for cell signaling, proper functioning of muscles, nerves, and the heart, bone and teeth formation, and is critical for hemostasis.
  - Total calcium includes *bound* calcium and the functional *free* (ionized) calcium
  - **Ionized calcium (iCA^{2+}) [ICA]** better reflects of Ca^{2+} status when there is a disturbance in the balance in bound vs. ionized Ca^{2+}, e.g., patients who are critically ill, receiving blood transfusions (citrate toxicity) or intravenous fluids, undergoing major surgery, or with blood protein abnormalities like low albumin.

- **Hematocrit**, the red cell fraction of the blood helps to evaluate oxygen carrying capacity.

SCOPE:

This procedure is for all Point of Care testing areas which utilize the GEM ® 5000 analyzer for testing. This is categorized by the FDA as moderately complex testing and all testing personnel must qualify under CLIA regulations, 42 CFR 493.1423.

PRINCIPLE:

The GEM® Premier 5000 system has two components including 1) an **analyzer**, which has the internal logic and processing power necessary to perform analysis and 2) the **GEM PAK**, a disposable, multi-use cartridge, which contains all necessary analytical components including, sampler, reagents, sensors, CO-ox optical cell, and waste bag, in gas tight chambers.
Upon sample aspiration, the **GEM PAK** uses peristaltic pumps move fluids into the sensor card and optical cell and eventually to the waste container. Along the fluid path, **potentiometric sensors** measure pH, pCO2, Na_+, K_+, and Ca_{++} and an **amperometric sensor** measures *p*O2. **Blood conductivity** is used to measure hematocrit (by exploiting the fact that plasma is more conductive than blood cells). **CO-Oximetry** involves chemically lysing the whole blood sample and then utilizing a **broad-spectrum spectrometer** to evaluate the sample at a variety of wavelengths. A full description of the detailed technical aspects of each method is available in the GEM 5000 Owner's Manual.

REAGENTS:

The GEM Premier 5000 PAK cartridge contains all reagents required for analysis. No reagent preparation is needed. The GEM PAK includes the following internal reagents.

- Reference Electrode Solution
- Lysing Solution (for CO-oximetry)
- Five (5) Process Control Solutions (PCS) A, B, C, D and E.

Store the GEM PAK according to the following chart (or current package insert, if different).

Reagent Pak	Storage temp	Onboard stability	Werfen Part Number
GEM 5K BG/Hct/Lytes/G/L/COOX 75 tests	15 to 25℃	31 days	00055407510
GEM 5K BG/Hct/Lytes/G/L/COOX 300 tests	15 to 25℃	31 days	00055430010
GEM 5K BG/Hct/Lytes/G/L/COOX 450 tests	15 to 25℃	31 days	00055445010
GEM 5K BG/Hct/COOX 450 tests	15 to 25℃	31 days	00055445004
GEM 5K BG/Hct/Lytes/G/L/COOX 600 tests	15 to 25℃	21 days	00055360010

MATERIALS AND SUPPLIES:

- Printer paper, 5 rolls per box (Werfen part number 00025000500)
- Clot catcher: Roche Diagnostics, Part #BP2243 – Disposable, single use device designed to prevent clots present in whole blood samples from entering the instrument. *Not for routine use.*

EQUIPMENT:

- GEM® Premier 5000 analyzer with barcode scanner
- APC Power Surge, Battery Pack
- Ampoule Breaker

SAMPLE COLLECTION:

Follow appropriate Nursing and Respiratory policies.

- **Arterial line collection**: Withdraw an appropriate initial (discard) volume to ensure the line contains only uncontaminated arterial blood, prior to actual sample collection. This process minimizes the chance of specimen contamination with intravenous solutions.
- **Syringe samples:** Mix thoroughly immediately after sample collection. Follow the syringe manufacturer's directions for mixing requirements. In the absence of instructions, mix the sample > 30 sec. by quick inversion of 1-2 inversions per second. Avoid vigorous shaking which can cause hemolysis and falsely elevated K_+ results.
- **Capillary specimens:** Warming the skin to approximately 42_o C will mimic arterialization of the blood sample. Sample collection is obtained by making a single puncture of 2.0 mm or less, allowing a droplet to form and collecting the blood from the center of the droplet. Wipe away the first drop to remove extracellular fluid that may interfere with results. Collect the sample. It is essential to properly dissolve heparin immediately after collection to prevent clotting. This can be achieved by

capping and rolling the capillary tube between fingertips (> 30 sec. or > 20 times), the use of metal mixing bars/fleas (> 10 times end to end) or other procedures according to the capillary manufacturer's recommendations. Samples are best run within 10 min. of collecting.

- **Venous/Mixed Venous:** Use the same mixing approach as arterial syringe specimens.

SAMPLE REQUIREMENTS:

Acceptable Patient Specimen Types:

Anti-coagulated whole blood from the following sources:

- Arterial, including umbilical cord
- Capillary
- Mixed venous blood
- Venous, including umbilical cord
- Arterial-mixed venous pairs

Acceptable Sample Types:

Acceptable Containers:

- 1-3 mL plastic, disposable blood gas syringe (blood gas, electrolytes or CO-oximetry)
- Green top (lithium heparin) non-gel, plastic collection tube (NAWB, KWB, ICA only).
- Capillary tube, non-glass preferred (neonates and arterialized samples).

Note: A bias on certain analytes was observed with RAM Scientific Capillary Tubes (p/n 06 0186) and Fleas (p/n 079503). DO NOT USE these capillary tubes and fleas with the GEM Premier 5000.

Specimen Volume:

Test Panel	**Minimum Sample Volume**	**Sample Stability (from draw)**
Blood Gas (pH, pCO_2, pO_2) chemistry (Na^+, K^+, Ca^{2+}), hematocrit and CO-oximetry (tHb, O_2Hb, COHb, MetHb, sO_2)	150 µL	**15 minutes** is preferable, up to 30 minutes
Co-oximetry only (tHB, O_2Hb, COHb, MetHb, sO_2)	100 µL	30 minutes
Capillary specimens for blood gas (pH, pCO_2, pO_2) chemistry (Na^+, K^+, Ca^{2+}), hematocrit	65 µL	10 minutes

Stability: Due to metabolic changes in whole blood, samples should routinely be analyzed immediately.

Mix well for 15 seconds after collection (3-5 inversions and roll between palms for 15 seconds) expel any excess air, walk to analyzer, mix well for 15 seconds again. Avoid vigorous shaking which can cause hemolysis.

Check for clotting by expelling a small amount of blood on a gauze before sampling.

Unacceptable Sample Types:

- Clotted samples
- Specimens older than 1 hour
- Grossly underfilled collection containers
- Incorrectly drawn or mishandled samples
- Incorrect anticoagulant

If results on these sample types posted, please note the error, and contact POCT.

MAINTENANCE:

Wipe the probe clean when it appears dirty.
Per the manufacturer, Werfen, there is no routine maintenance. Follow the Operator's Manual for as needed cleaning, replacing the printer paper or replacing a fuse.

CALIBRATION:

The GEM Premier 5000 GEM PAK is a self-contained analyzer (closed analytical system) that is manufactured to specifications. It cannot be user calibrated.

With each newly installed GEM PAK, the GEM Premier 5000 system reads and records all factory-assigned information, including lot number, expiration date, test menu, sample capacity, and assigned values and acceptable ranges for all process control solutions. The instrument then automatically tests the electronic software performance of the system and initially verifies calibration. A status indicator will appear at the top of the screen. If all sensors are operating properly, the "Ready" message will appear at the top of the screen when the startup is complete. The analyzer attempts correction whenever, performance specifications are unmet and disables individual analytes or will reject the cartridge if performance cannot be verified.

CALIBRATION VERIFICATION:

Auto PAK Validation (APV): After GEM PAK installation and start-up, the GEM Premier 5000 will automatically perform calibration validation utilizing two (2) independent on-board solutions, traceable to NIST standards, CLSI procedures or internal standards.

Process Control Solutions (PCS) D and E (also see *Quality Control)* are used to validate the calibration of each cartridge prior to sample analysis.

External materials can be used as needed to troubleshoot the test system. Combinations of the following materials are acceptable to verify calibration at low, midpoint and high values across the reportable range.

- **Performance Verification Product (PVP)** 5-point calibration verification materials (for pH, pCO_2., pO_2, Na^+, K^+, Ca^{2+} and tHb).

- **Eurotrol** for verification of very high (hyperbaric) and very low (hypobaric) pO2 readings that exceed the range for other calibration verification materials.
- **RNA Medical CO-Oximeter Calibration Verification Controls** (4 to 5-point verification materials for tHb, O_2Hb, COHb and low MetHb.
- **GEM System Evaluator (GSE)** levels 1, 2 and 3 external quality controls (for pH, pCO_2., pO_2, Na^+, K^+, Ca^{++}, tHb, O_2Hb, COHb and MetHb); using one or more levels with higher values for MetHb is acceptable for verifying a higher range for MetHb.

The CLIA Lab Director has determined that the manufacturer's published performance specifications for these materials are sufficient to assure adequate calibration.

Store reagents according to the product insert:

Reagent	**Storage**	**Closed Container Stability**	**Open Container Stability**
PVP	2-8℃ or Room Temp (15-25℃) Do not freeze.	See labeled expiration (maximum 3 mo. at RT) Sensitive to ambient temperature variation	Single Use Only Equilibrate at 22℃ ±1℃ for 8 hours prior to use (pO_2 varies by~1%/℃ outside of this range)
RNA Medical Co-OX Cal Ver	2-8℃	See labeled expiration	Analyze immediately Single Use Only
GSE 1,2,3	2-8℃ or Room Temp (15-25℃) Do not freeze.	See labeled expiration (maximum 6 mo. at RT) Sensitive to ambient temperature variation	Single Use Only Equilibrate at 22℃ ±1℃ for 8 hours prior to use (pO_2 varies by~1%/℃ outside of this range)

QUALITY CONTROL:

Intelligent Quality Management 2 (iQM2®) is used as the primary quality control and assessment system (based on statistical process control). Each single, multiuse disposable **GEM PAK** is a closed cartridge system. iQM2 is designed to provide continuous monitoring of the analytical process before, during and after sample measurement with real-time pattern recognition (PR), automatic error detection, automatic correction of the system and automatic documentation of all corrective actions. iQM2 is designed to maximize the probability of error detection and minimize the time to error detection while minimizing the probability of false rejection.

Once the GEM PAK start-up and APV is completed, iQM2 automatically performs five (5) types of quality checks to continuously monitor the performance of the GEM PAK's sensors, CO-Ox, and reagents throughout the cartridge use-life. These checks include 1) ***System,*** 2) ***Sensor/CO-ox,*** 3) ***IntraSpec*** , 4) ***Pattern Recognition*** and 5) ***Stability*** checks.

For full descriptions, refer to the Owner's Manual.

The CLIA Director has determined that the manufacturer's ranges for all controls are narrow enough to provide results with meaningful clinical applications.

METHOD COMARISON & LINEARITY:

At least every six months, a method correlation study is performed between the POCT GEM 5000s and with the Clinical Lab primary GEM 5000 and the for the lactate and glucose, with the Core Lab Advia 1800 instrument. This comparison also challenges the linear range of each analyte. This comparison is evaluated with the following acceptability criteria:

Allowable Total Error (TEa) Table

	CLIA/CAP Limits	**ZSFG POCT TEa**
Blood Gas		
pH	± 0.04	± 0.04
pCO2 (mm Hg)	± 5 mm Hg or 8% (whichever is greater)	± 5 mm Hg or 8% (whichever is greater)
pO2 (mm Hg)	± 3SD	± 9 mm Hg or 10%
CO-oximetry		
THB (g/dL)	± 7%	± 7%
OSAT (%)	± 3 or ± 3SD (whichever is greater)	± 3 (absolute %)
COHB (%)	± 3 or ± 3SD (whichever is greater)	± 3 (absolute %)
METH (%)	± 2	± 2 (absolute %)
sO2 (%)	-	± 3 (absolute %)
Hematocrit		
Hct (%)	± 6%	± 6%
Electrolytes		
Na^+ (mmol/L)	± 4.0	± 4.0
K^+ (mmol/L)	± 0.5	± 0.5
iCa^{2+} (mmol/L)	± 3SD	± 0.15
Glucose (mg/dL)	± 6 or ± 10% (whichever is greater)	± 7%
Lactate (mmol/L)		± 30%

Note: HHb (%) is not reported but used to derive sO2. Whereas modest changes in HHb typically show proportional changes in sO2, significant changes in HHb, may show even greater changes in sO2. Optimally total error (TE) for HHb would be within ± 2 (absolute); a TE within ± 3 (absolute) is generally acceptable when a concurrent sO2 is also within ± 3 (absolute).

The CLIA Laboratory Director has determined that the manufacturer's published TEa limits for this FDA-cleared test system are narrow enough for routine iQM2 monitoring and will provide results with meaningful clinical applications.

PROFICIENCY TESTING:

Using the Proficiency sample type minimizes the effect that the matrix and preservatives of CO-oximetry and bilirubin proficiency materials may have on the electrochemical sensors, which could result in the analyzer entering an extended fixing cycle following exposure. The Proficiency mode for CO-Oximetry and bilirubin does not alter the measurement mode for those analytes but does mover the sample into the OC-ox/tBili measurement area faster so that sensors are exposed for a shorter period. Proficiency testing materials are still analyzed in the same manner as a patient sample, even when using Proficiency mode. When used for proficiency testing, follow the instructions accompanying proficiency testing materials.

PROTOCOL:

The Status bar signals different conditions for the GEM Premier 5000 system:

Green READY
Yellow User specific action needed
Red Analyzer is locked
Blue Analyzer is performing a function

Replacing the Cartridge (PAK) and Warm-up Procedures:

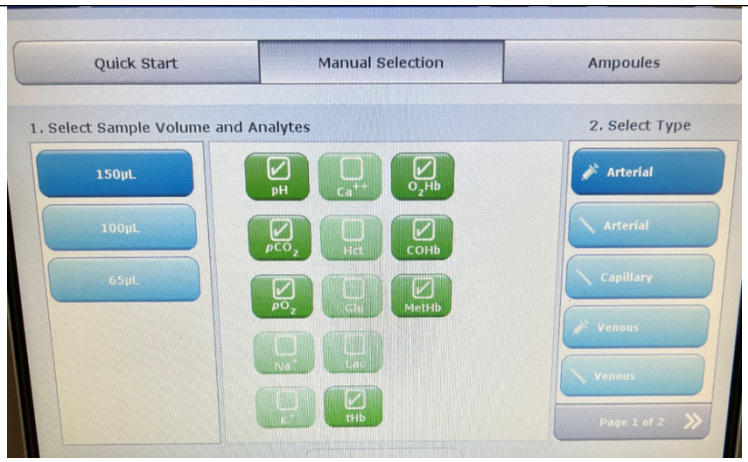
The GEM Premier 5000 automatically notifies operators when it is time to remove the Cartridge: When sample capacity has been reached, or when cartridge use life expires. In each case the door will automatically open and display a message to the operator to "REMOVE CARTRIDGE." Cartridges may also be removed prior to maximum onboard life or test capacity. Examples are leakage or when the sensor is permanently disabled, and its functionality cannot be recovered. In this case, notify a Unit Supervisor or Manager before changing cartridge. Also notify Technical Support at Werfen of the cartridge error.

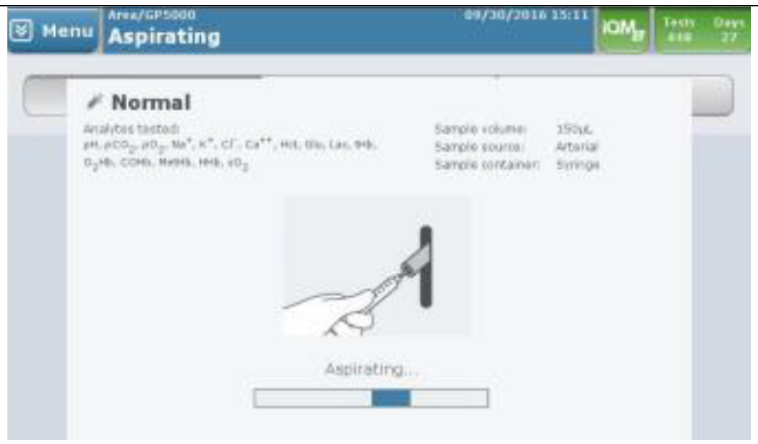
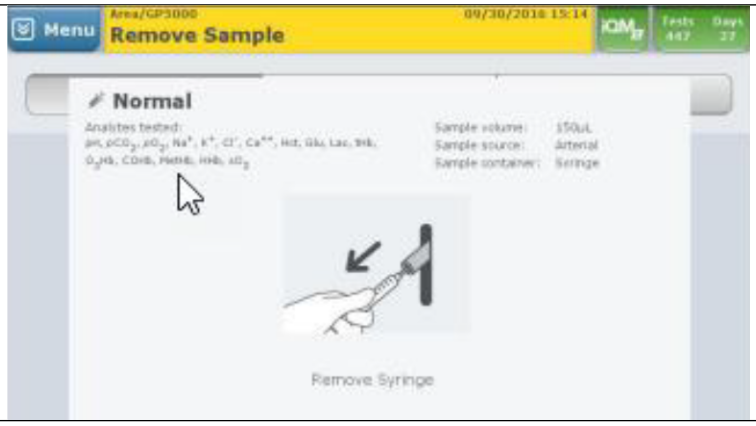
Step	Action	Detail
1	If the analyzer is OFF, press the power switch to turn it ON.	
2	Press Open Door on the touch screen.	The door will release and open slightly.
3	Manually move the door all the way to the left.	
4	Verify that the new cartridge is not expired and unpack the cartridge from	CAUTION: Do not use an expired or leaking cartridge.

	its protective wrapper. Remove the cover from the pump winding area. Check the inside of the protective wrapper to be sure that it is dry.	
5	Position the cartridge with the gray sampling area facing forward.	
6	Push the cartridge in until you feel resistance.	Please note that approximately one inch of the cartridge will extend beyond the front of the analyzer.
7	Guide the analyzer door to the right to close it and move the cartridge into its final position.	Cartridge warm-up requires 40 minutes. During this time, the sensors will hydrate, and the analyzer will perform internal checks and calibration.

Running Samples

Step	Action	Detail
1	Samples can be analyzed when the instrument screen displays the "READY" banner.	
2a	Select desired Panel from Quick Start menu only (except for NICU who can use Manual Selection).	Sample type (venous, arterial, cord arterial, etc.) is built into the panel (different than GEM 4000's), **so be careful of what panel you chose** before sampling.

2b	Manual Selection: NICU only Select the sample volume, the analytes and the sample type. NOTE: it is important to select all analytes associated with the panel, otherwise the entire panel will not post to Epic. Users cannot just select COHb or pH, for example.	
	For capillary samples:	150uL volume can be used for both capillary and syringe samples and all analytes are available 100uL volume is for both capillary and syringe samples, but only includes co-oximetry. 65uL volume is for capillary tube samples only and does NOT include co-oximetry.
3	Before sampling, notice what panel, panel analytes and sample type that you have chosen. (A demo "Normal" panel and Arterial sample type is shown here).	
	If it is wrong…	**Then, hit Cancel.** Wait and let it process until it returns to the Quick Start menu and try again, approximately a 1 min wait time.

4	The GEM prompts "Hold Syringe over end of sampler", insert blood syringe over lighted probe, and hit Start Aspiration. The GEM will aspirate sample displaying a Message on the blue menu bar "Aspirating Sample"	
6	Remove the sample when prompted on screen, the light flashes and you hear a beep-beep.	
7	The **only required field is the CSN/account number**, scan in from sample.	Demographics should query on screen. See Troubleshooting section below if they do not.
8	**Verify the patient's information using PPID – positive patient ID.**	MRN, full name, DOB should match label on specimen!
9	**Results will auto verify.**	Print results if needed. You can also return to that result from the home screen by going to **Menu → View Last Result**

CALCULATIONS:

All calculations are performed by the GEM 5000. Consult the GEM 5000 Operators Manual for a complete list of equations used.

REFERENCE INTERVAL:

Blood Gas Reference Intervals

ANALYTE	ARTERIAL	VENOUS	CAPILLARY	CORD BLOOD ARTERIAL	CORD BLOOD VENOUS
pH					
Newborn				7.10 - 7.38	7.20 - 7.46
0 to 6 mos	7.25 - 7.45	7.32 - 7.42	7.31 - 7.47		
> 6 to 12 mos	7.30 - 7.45	7.32 - 7.42	7.31 - 7.47		
> 1 yr	7.35 - 7.45	7.32 - 7.42	7.35 - 7.45		
pCO_2 (mmHG)					
Newborn				35 - 74	28 - 57
0 to 12 mos	27 - 40	41 - 51	30 - 50		
> 1 yr	35 - 45	41 - 51			
pO_2 (mmHG)					
Newborn	50 - 90		30 - 60	6 - 30	16 -43
0 to 12 months		35 - 50	30 - 60		
> 1 day to 12 months	80 - 100	35 - 50	30 - 60		
> 1 yr to 65 yrs	80 - 100	25 - 40			
> 65 yrs	75 - 85	25 - 40			
HCO_3^-, Actual (mmol/L)					
0 to 1 mo	17 - 24	18 - 24			
> 1 mo to 1 yr	19 - 24	18 - 24			
> 1 yr	22 - 26	22 - 29			
Base Excess (BE, ecf, mmol/L) ***GEM Printout (negative numbers)***					
Newborn				-10 to +1	-10 to +2
0 to 1 mo	-10 to -2	-10 to -2	-10 to -2		
1 to 12 mos	-7 to -1	-7 to -1	-7 to -1		
> 1 yr	-2 to +3	-2 to +3	-2 to +3		
Base Excess (BE, ecf, mmol/L) ***Sunquest ****					

Newborn				0 - 1	0 - 2
0 to 1 mo	None	None	None		
1 to 12 mos	None	None	None		
> 1 yr	0 - 3	0 - 3	0 - 3		
Base Deficit (BD, mmol/L) ***Sunquest ****					
Newborn				0 - 10	0 - 10
0 to 1 mo	2 - 10	2 - 10	2 - 10		
1 to 12 mos	1 - 7	1 - 7	1 - 7		
> 1 yr	0 - 2	0 - 2	0 - 2		

***Base Excess (BE)** may be negative or positive. In the table above, BE relate to how this value will appear on the GEM 5000 Print Out. Sunquest (SQ) is unable to display negative numbers. When BE is positive it will display in SQ as a positive value. When BE is negative, meaning that there is a base deficit (BD), the BD will be display in Sunquest as a positive value and the BE field will display as "None." Reference intervals in SQ for BE and BD include only zero or positive range values.

CO-Oximetry Reference Intervals

	All Whole Blood Samples	
Analyte	**Male**	**Female**
THB (g/dL)		
>18 yrs	13.3 - 17.7	11.7 - 15.7
12 – 18yrs	13.0 - 16.0	12.0 - 16.0
OSAT(Arterial)	93 - 100%	
SO2 (Arterial)	94 – 100%	
COHB (%)	0.5 - 1.5% (non- smokers)	
MetHb (%)	< 1.5%	
Oxygen Content O_2ct (all ages)	15 – 23 Vol %	
Infant Care Center		
	OSAT (%)	**SO2 (Arterial)**
0 to 4 hours	85 – 90%	85 – 90%
> 4 hours	93 – 100%	94 – 100%
COHB (%)		
0 – 12 mo.	0.5 - 1.5 %	
MetHb (%)		
0 – 12 mo.	< 1.5 %	

Pediatric Reference Ranges for THB	
Age	**HGB (g/dL)**
<1 day	13.5-19.5

1-7 days	13.5-22.5
8-14 days	12.5-21.5
15 days - <1 mo	10.0-20.5
1 mo - <2 mos	9.0-18.0
2 mo - <3 mos	9.0-13.5
3 mo - <6 mos	9.5-13.5
6 mos - <2 yrs	10.5-13.5
2 yrs - <6 yrs	11.5-13.5
6 yrs - <12 yrs	11.5-15.5

Electrolyte Reference Intervals

ANALYTE	**ALL WHOLE BLOOD SAMPLES**	
ELECTROLYTES (WHOLE Blood)		
Sodium (Na^+) (mmol/L)	133 - 146 mmol/L for all ages	
Potassium (K^+) (mmol/L)		
0 – 2 weeks	3.7 - 5.9 mmol/L	
2 weeks – 1 yr	4.1 - 5.3 mmol/L	
1 – 16 yrs	3.4 - 4.7 mmol/L	
> 16 yrs	3.5 - 5.1 mmol/L	
Ionized Ca^{++} (mmol/L)		
0 – 12 mos	0.95 - 1.50 mmol/L	
> 1 yr	1.12 - 1.32 mmol/L	
Glucose (mg/dL), Random (Whole Blood & Fingerstick)		
Newborn – 1 year	50 – 150 mg/dL	
>1 year	70 – 199 mg/dL	
>1 year, Diabetes	≥ 200 mg/dL	
Lactate (mmol/L)		
	ARTERIAL	**VENOUS**
0 – 12 months	0.3 – 2.2 mmol/L	0.3 – 2.9 mmol/L
>1 year	0.5 – 1.6 mmol/L	0.5 – 2.2 mmol/L

Hematocrit Reference Intervals

Analyte	**All Whole Blood Samples**	
HCT (%)	**Male**	**Female**
Adult		
>18 yrs	39.8 - 52.2%	34.9 - 46.9%

Pediatric		
Birth	42.0 - 60.0%	
1-7 days	42.0 - 67.0%	
8-14 days	39.0 - 66.0%	
15-30 days	31.0 - 66.0%	
1-2 mos	28.0 - 55.0%	
2-3 mos	28.0 - 42.0%	
3-6 mos	29.0 - 41.0%	
0.5-2 yrs	33.0 - 39.0%	
2-6 yrs	34.0 - 40.0%	
6-12 yrs	35.0 - 45.0%	
12-18 yrs	37.0 - 49.0%	36.0 - 46.0%

CRITICAL VALUES:

All critical values MUST be acted upon immediately, notify the provider/ clinical team immediately and document notification in the patient's medical record (EPIC).

	Source				
Analyte	**Arterial**	**Venous**	**Capillary**	**Cord Blood Arterial**	**Cord Blood Venous**
pH	<7.20 or >7.55	<7.20	<7.20 or >7.55	<7.0	<7.0
***p*CO$_2$ (mmHg)**	<25 or >65	>5	<25 or >65	–	–
***p*O$_2$ (mmHg)**					
> 1 month	<40	–	–	–	–
Neonate 0 to 30 days	<40 or >100	–	<40 or >100	–	–
Base Deficit (BD, mmol/L)					
Neonate 0 to 30 days	>10	–	>10	>10	>10
Na$^+$ (mmol/L)	<125 or >155				
K$^+$ (mmol/L)	<3.0 or >6.0				
Ionized Ca^{++} (mmol/L)	<0.8 or >1.55				
COHB (%)	>14.9%				
MetHb (%)	>14.9%				
THB (g/dL)	**0-7 days:** <7g/dL or >22.5 g/dL				

	8-30 days: <7g/dL or >21.5 g/dL **>30 days to adult:** <7g/dL or >20 g/dL

Metabolic	
Glucose (mg/dL)	<50 or >500
Lactate (mmol/L)	>3.9

METHOD PERFORMANCE SPECIFICATIONS AND METHOD LIMITATIONS:

REPORTABLE RANGES:

Analyte	Reportable Ranges
pH	6.80 – 7.80
pCO_2	10 – 125 mmHg
pO_2	20 – 610 mmHg
Na^+	100 – 180 mmol/L
K^+	1.0 – 10 mmol/L
iCa^{++}	0.5 – 3.0 mmol/L
Gluc	20 – 680 mg/dL
Lac	0.5 – 15.0 mmol/L
Hct	15 – 67 %
tHb	5.0 – 22.5 g/dL
O_2Hb	0.0 – 100 %
COHb	0.0 – 100 %
MetHb	0.0 – 100 %
Derived Parameter Reportable Range	
HCO_3 Std	3.0 – 60. 0 mmol/L
HCO_3	3.0 – 60. 0 mmol/L
TCO_2	3.0 – 60. 0 mmol/L
BEecf	-30.0 to 30.0 mmol/L

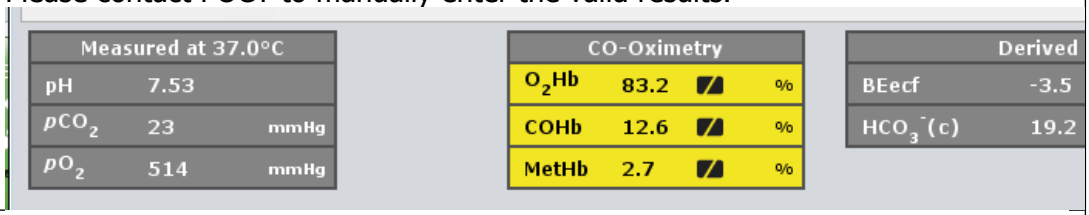
For results outside of verified linear range, they will be > (greater) or < (less than) reportable range, as appropriate. Related calculated values will be reported as NCAL (not calculated).

Limitations and Interferences

Condition	Risk	Mitigation
Drugs/Chemicals	Drugs/Chemicals may change analyte concentration.	A complete list is found in the GEM 5000 Operators Manual.
Vacutainer tubes with gel separator	Gel separator can significantly elevate COHb levels.	Avoid tubes with a gel separator.
Sulfhemoglobin	Samples results may be outside specification claims.	The instrument may correct for lower levels of

		sulfhemoglobin.
Triglycerides (Intralipd)	Lipemia or Intralipid fat emulsion in I.V (parenteral) nutrition may cause sample results to be outside specifications.	Sampling at a different time may help.

TROUBLESHOOTING

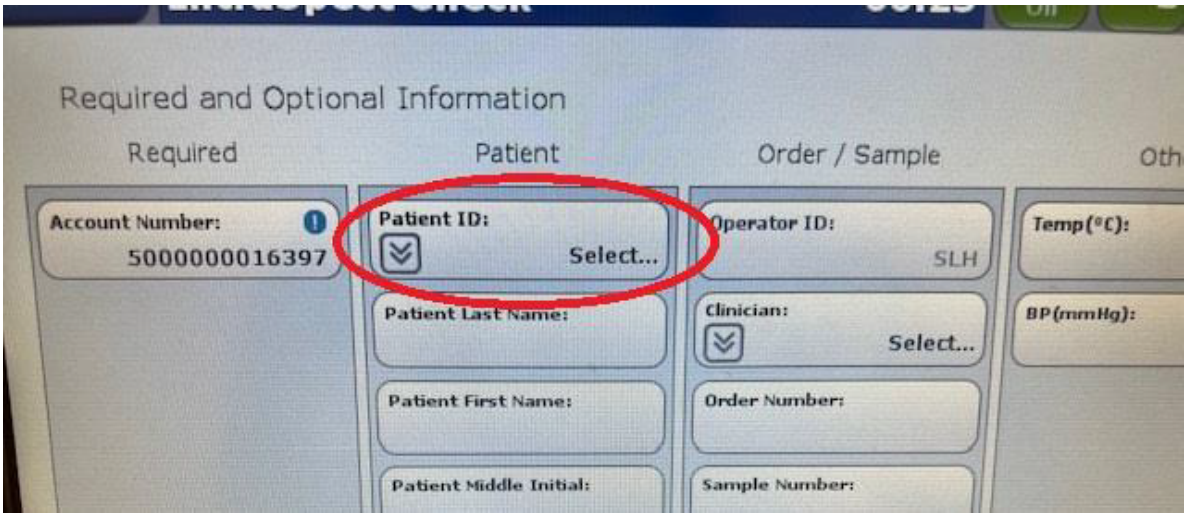
Error	Detail
Cartridge or Analyte Failures	Specific analytes failing CVP warm up or going out later: • After warmup, single analytes can fail CVP and the analyte will be red on screen and red in the panel they are a part of in the Quick Start menu. The analyzer/cartridge is still usable, you will not get results on the failed analyte, and nothing will cross into Epic for that analyte. **Notify POCT of failed cartridge and serial number if possible – we get a replacement shipped for free.** • If an analyte goes out later, hours or days after being put into use, they will also turn red on the screen and red in the panel that they are a part of in the Quick Start menu. All earlier patient results released are acceptable because of the continuous monitoring of iQM processes. Notify POCT of the failed cartridge – there possibly can be a credit.
Incalculable results (INCALC)	If the COOX and/or a single analyte shows Incalculable results, it will auto verify and post to EPIC as "Results Not Valid." If many analytes have this error, all the results will not auto verify.
Interfering Substances	All of the exception flags (except for any that say "Result Corrected"), **all** results will not auto verify. Please contact POCT to manually enter the valid results. 
Exception Flags List	Exception Flags on Results Screen and on Printed Reports Exception Flag / Exception Flag Description incalculable — Result Incalculable A — Absorbance Error S — Result Corrected for Sulphaemoglobin T — High Turbidity Detected Interference Detected Micro Clot Detected Temporary Sensor Error
Suspect Results	Repeat with a new sample or send a new sample to the Clinical Laboratory for analysis.

	Common considerations: Did you mix the sample well, according to the procedure? Did you check for a clot prior to analyzing the sample? Is it run within the allowed timeframe or are there delays in testing?

RESULT REPORTING/ENTRY:

Results will auto verify and transmit to the patient medical record (EPIC) through the Laboratory Information System (Sunquest).

If the patient demographics do not load into the Patient Information on the GEM 5000 after scanning the patient CSN barcode, manually type the patient MRN into the Patient ID field. This indicates that the patient was identified with PPID (positive patient ID) using two patient identifiers.



If the wrong patient ID was scanned, or the wrong sample type was selected, immediately notify the provider of the wrong patient sample date and time. Recollect and re-test correctly. Notify the POCT by email or phone call to be corrected in EPIC. Provide the following information:

- Your name, and provider's name that you alerted
- GEM location
- MRN, and patient name
- Date/time sample ran on the GEM
- Briefly how the error occurred

AUTO-VERIFICATION

Auto-verification function is validated prior to use and then reviewed and validated annually.

Other circumstances which require re-validation:

- following any LIS modifications which could affect the AV functions (identified by the LIS Supervisor),
- following instrument software modification which could affect the AV functions,
- any modifications in the AV criteria or procedures (only the changes need to be revalidated),
- following a malfunction of the AV functions or any corrective action of AV functions.

Documentation is reviewed by the POCT coordinator, and the Medical Director will approve the computer algorithm.

AV Failure: If any result is auto-verified which appears to be an error, or any observed malfunction in the auto-verification process, notify POCT immediately.

REFERENCES:

- GEM® Premier 5000 Operator Guide
- GEM® Premier 5000 Analyzer SOP

RELATED DOCUMENTS:

- LIS procedure Autoverification Policy and Procedure (No. 48667.210)