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Policy Area:	*Lab / Chemistry*
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GEM 4000/3500 Whole Blood Sample Analysis, R-W-CH-5040-02

PURPOSE

To define how to analyze patient whole blood samples and serous body fluids on the GEM Premier 4000 and GEM 3500 instrument with Intelligent Quality Management.

BACKGROUND

The GEM Premier 4000/3500 analyzer with iQM is a portable critical care system used to rapidly analyze whole blood samples to provide quantitative measurements of pH, blood gases, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, and CO-Oximetry (tHb, O2Hb, COHb, MetHb, and HHb). 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. Aliquots from serous body fluids have been validated for pH testing only.

EQUIPMENT

GEM Premier 4000 Instrument
GEM 3500 Instrument
Blood Transfer Device
3 mL syringe with luer lock

REAGENTS

GEM Premier 4000 PAK® Cartridge with iQM
GEM 3500 Cartridge Pak

REAGENT STORAGE

Cartridges are stored at room temperature and are stable until the expiration date listed on the package. Once placed on the instrument the cartridge is stable for 30 days or the indicated number of tests, whichever is first.

CALIBRATION

The GEM Premier 4000 automatically performs three types of calibrations: one-point calibrations, two-point

calibrations, and low oxygen calibrations. During these calibrations, the instrument adjusts each sensor's performance to ensure correct operation. Calibrations will be performed after each analysis, periodically during idle time, and on demand when needed. No operator intervention is required.

SPECIMEN COLLECTION AND HANDLING

TEST	VOLUME	TUBE	SAMPLE HANDLING	TIME LIMIT
Lactic Acid	150 uL	Na Oxalate/ K Fluoride (Gray)	Whole Blood Room Temperature	Test within 15 minutes
			Whole Blood Received on ice	Test within 2 HOURS
Ionized Calcium and pH	150 uL	Lithium heparin	Whole Blood Room Temp or on ice	Test within 3 hours.
			Spun and plasma refrigerated (Note: tube not opened prior to testing)	Test *plasma* within 24 hours
pH, Body Fluid	150 uL	Capped Aliquot tube with minimal dead space without anticoagulants	Spun and fluid refrigerated or frozen -20?C.	Rm Temp: 1 hour tightly capped and unopened Refrigerated: 1 day, capped. Frozen: 6 mo.
Sodium Potassium Chloride TC02 *(calculated)* Hemoglobin Hematocrit Glucose	150 uL	Lithium heparin	Whole Blood Room Temp	Received and tested within 15 minutes
			Whole Blood on ice	Test within 3 hours
			Spun and plasma refrigerated	Test *plasma* within 8 hours; note: ***Hgb/ HCT invalid***
Carboxyhemoglobin	150 uL	Lithium heparin	Whole Blood Room Temp or on ice	Received and tested within 30minutes
Methemoglobin	150 uL	Lithium heparin	Whole Blood Room Temp or on ice	Received and tested within 30minutes

UNACCEPTABLE SPECIMENS

A specimen is considered unacceptable if it is not analyzed within the validated time frames listed above, is not labeled with two FHS patient identifiers, is in the incorrect anticoagulant, or if specimen is clotted. Specimens should not have been exposed to air prior to testing. Highly viscous body fluids are unacceptable and the use of hyaluronidase is unacceptable. Blood transfer devices should be removed from the sample after testing to prevent air exchange.

Sample Preparation

Before analyzing the sample, it is important that whole blood be mixed properly. Invert the sample tube gently for 5 seconds before sampling. Full tubes are preferred. Any samples in syringes, that are not tested immediately, should be inverted and rolled in between the palms before aspiration.

STEPS

Select Normal by pressing the "Normal/Micro" toggle button on the upper left corner of the screen.
Note: Micro sampling is not appropriate for whole blood venous samples.

Sampling steps when LIS interface is up

1. From Main GEM Screen.
2. Scan the patient LIS barcode label. The Order Detail screen should come up. For body fluid specimens for pH, follow instructions below for Sampling Steps when the LIS Interface is down.
3. Verify the patient information on the Order Detail screen.
4. Press the "RUN THIS ORDER" button on the screen.
5. Mix the sample thoroughly by gently inverting the tube 5-10 times. If clots are suspected, check the sample. Obtain another sample if needed.
6. Press "GO!"
7. The sample probe will emerge from its home position.
8. Immerse or insert sample probe into sample. Ensure that the probe extends far enough into the syringe and sample to aspirate 150 uL of the sample. Press OK.
9. The analyzer will aspirate the sample and then display "Remove Sample" when sampling is completed.
10. Press "View Results" Acceptable results will be sent across the LIS interface and verify the result in the LIS, as performed at your facility.

Sampling steps when LIS interface is down

1. Select test or panel of tests to be performed.
2. Specify the sample type arterial, capillary, mixed venous, venous or other (see in section 2 of the menu).
3. Mix the sample thoroughly by gently inverting the tube 5-10 times. If clots are suspected, check the sample. Obtain another sample if needed.
4. Place a blood transfer device onto the vacutainer tube.
5. Invert the tube gently to mix. Connect the syringe to the connector on the transfer device.
6. Withdraw sample from the tube using the syringe and blood transfer device, taking care not to draw

bubbles, or dead air volume, into the syringe.

7. Press "GO!"
8. The sampler will emerge from its home position.
9. Present the syringe with sample to the Gem sampler, and press OK.
    - The sampler should be inserted far enough into the syringe to allow 150 uL to be aspirated, but not so far that the sampler touches the bottom of the syringe.
    - Make sure that the sampler is below the level of the blood in the syringe.
10. The system will aspirate the sample and emit an audio prompt when aspiration is complete. Remove the container promptly. The probe will retract into the system.
11. Select the "Enter Information" tab. Enter the Operator ID (Tech ID) and scan the LIS barcode label into the sample ID field. Enter the full name for two patient identifiers. Comments may also be entered if required.
12. Dispose of sample syringes in a biohazard waste container once testing is completed.
13. "View Results" cannot be accessed until all required fields are completed. Press "Accept". The results will then print. Enter results into LIS manually and verify the result in the LIS, as performed at your facility. If not autoverified, keep a copy of the GEM printout with Beaker print screen of patient results and document critical call in Comm Log. If unable to contact provider/RN, Pre-Lim verify until contact can be made and document call in Comm Log.

RESULT NOTES

- Report measured result, not the derived result from GEM.
- Other exception flags may be found in the Operator's Guide, section IX.
- Sample results that should not be included in the data base can be excluded by pressing "Exclude". The operator may then rerun the sample or collect a new sample to run.
- To search the GEM 4000 database for patient history, review the Operator's Guide section X.

NORMAL REFERENCE RANGE

ANALYTE	AGE	NORMAL RANGE	CRITICAL
Lactic Acid, whole blood	Adult	0.5-2.0 mmol/L	> 4.0
NA, whole blood	Adult	135-153 mmol/L	<120, >155
K, whole blood	Adult	3.5-5.3 mmol/L	<3.0, >6.0
CL, whole blood	Adult	98-109 mmol/L	
CA, ionized whole blood	Adult	1.11-1.33 mmol/L	<0.89, >1.51
pH, blood	Adult	7.31-7.41	
pH, body fluid	Adult	6.90 – 7.60	
COHb	Adult	0.5-1.5 %	
MetHb	Adult	<3.0	
CO2, whole blood	Adult	22-32 mmol/L	<10, >45
GLU, whole blood	2 Days	40-90	<40, >200

ANALYTE	AGE	NORMAL RANGE	CRITICAL
GLU, whole blood	Adult	65-99	<50, >450
HCT, whole blood	Adult- Male	38-49 %	<22, >65
HCT, whole blood	Adult-Female	36-43 %	<22, >65
HCT, whole blood	Neonatal Ranges		
	0 day – 1 day	50 -78%	<20 or >65
	1 day – 2 wks	38 - 70%	<20 or >65
	2 wks – 4 wks	32 - 54%	<22 or > 60
	4 wks – 8 wks	26 – 40%	<22 or > 60
	8 wks – 12 wks	27 – 39%	<22 or > 60
	12 wks – 6 mo	30 – 41%	<22 or > 60
	6 mo – 1 yr	31 – 41%	<22 or > 60
HCT, whole blood	Pediatric Ranges		
	001 YRS to 5 YRS	31 – 43 %	<22 , >65
	5 YRS to 9 YRS	33 – 44 %	<22 , >65
	9 YRS to 12 YRS	36 – 45 %	<22 , >65
	12 YRS to 14 YRS	37 – 46 %	<22 , >65
	14 YRS to 18 YRS	38 – 52 %	<22 , >65
Hemoglobin, whole blood	Adult- Male	13.1 – 16.5 g/dL	<7.0, >20.0
	Adult-Female	12.0 – 14.7 g/dL	<7.0, >20.0
	Neonatal Ranges		
	0 day – 1 day	15.9 – 22.5 g/dL	<7.0, >21.6
	1 day – 2 wks	12.8 – 21.8 g/dL	<7.0, >21.6
	2 wks – 4 wks	10.1 – 18.3 g/dL	<7.0, >20.0
	4 wks – 8 wks	8.9 – 13.2 d/dL	<7.0, >20.0
	8 wks – 12 wks	9.5 – 13.1 g/dL	<7.0, >20.0
	12 wks – 6 mo	9.9 – 13.9 g/dL	<7.0, >20.0
	6 mo – 1 yr	11.0 – 14.1 g/dL	<7.0, >20.0
Hemoglobin, whole blood	Pediatric Ranges		
	1 yr – 5 yrs	11.0 - 14.5 g/dL	<7.0, >20.0
	5 yrs – 9 yrs	11.5 – 14.6 g/dL	<7.0, >20.0
	9 yrs- 12 yrs.	12.0 – 15.1 g/dL	<7.0, >20.0
Female	12 yrs – 14 yrs	12.0 – 15.3 g/dL	<7.0, >20.0
Male	12 yrs – 14 yrs	12.5 – 15.8 g/dL	<7.0, >20.0
Female	14 yrs – 18 yrs	12.0 – 15.4 g/dL	<7.0, >20.0
Male	14 yrs – 18 yrs	13.0 – 17.0 g/dL	<7.0, >20.0

LIMITATIONS

- Results that appear to be inconsistent with patient history, therapy, or condition should be viewed as questionable and the test should be repeated on the laboratory backup method.
- Follow normal department procedures and follow-up actions for hemolyzed samples if hemolysis is noted after reporting of results.

FHS ANALYTICAL MEASUREMENT RANGE (AMR)

Whole Blood Analyte	Reportable Range
NA+	106.0-174.0 mmol/L
K+	1.2-10.10 mmol/L
CL-	69.0-152.0 mmol/L
Glu	16.0- 691.0 mg/dL
HGB	6.3-20 g/dL
HCT	18-63%
LAC	0.4- 16.0 mmol/L
pH	6.90-7.74
COHb	0.1-24.5%
MetHb	0.1-27.3%
pCO2	19.0-121.0 mmHg
pO2	37.0-572.0 mmHg
CA++	0.24-2.98
tHb	6.3-20.0

INTERFERING SUBSTANCES AND LIMITATIONS FOR GEM

Samples with questionable results on the GEM will be spun down, and immediately run on the chemistry analyzer, or with pH paper for body fluid pH's.

Limitations	Description
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 Reticulocyte Counts	Samples will deteriorate more rapidly, even when kept in ice water.
Improper Mixing	Errors will be introduced for measurement of hematocrit and CO-Ox parameters if the sample is not properly mixed prior to measurement.
Exposure to Air	Tubes should be full to minimize the exposure to air; Tubes should remain

Limitations	Description
	capped until testing; blood transfer devices should be removed after sampling to prevent air exposure.

The following substances may show noticeable interference with certain channels on the GEM Premier 4000/3500 analyzer, causing falsely elevated results.

Substance	Affected Analyte	Substance Concentration Producing Interference
Benzalkonium*	Ca++	5 mg/L
Bromide	Cl^-	10 mmol/L
Cyanomethemoglobin**	CO-Oximetry	>4%
Dopamine	Glucose, lactate	5 mg/dL
Dobutamine	Glucose, lactate	2 mg/dL
Fluoride	Cl^-, lactate	500 mg/dL
Glycolic acid	Lactate	1 mmol/L
Hemoglobin Based Oxygen Carriers (Hemopure***)	Hematocrit	3.2 g/dL
Hydroxyurea	Glucose, lactate	0.8 mg/dL
Iodide	Cl^-	3 mmol/L
Isoniazide	Glucose, lactate	5 mg/dL
Oxalate	Cl^-, lactate	500 mg/dL
Salicylate	Cl^-	4 mmol/L
Sulfhemoglobin**	CO-Oximetry	>3%
Thiopental*	PCO2, Ca++	30 mg/L
Turbidity**	CO-Oximetry	5% based on turbidity created by Intralipid**** fat emulsion
Uric acid	Glucose	20 mg/dL

*The GEM Premier 4000/3500 analyzers with iQM employs failure pattern recognition checks. These checks include detecting the presence of positively charged lopophilic compounds (e.g., benzalkonium) and negatively lipophilic compounds (e.g., thiopental). The GEM Premier 4000/3500 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 tested drugs may interfere **with glucose determination**, causing falsely low readings:

Drug	Interference Observed
Oxalate	1000 mg/dL
Fluoride	500 mg/dL

REFERENCES

Instrumentation Laboratory GEM Premier 4000 Reference Guide, October 2006.

Instrumentation Laboratory GEM Premier 4000 Training Guide, October 2006

Instrumentation Laboratory GEM Premier 4000 Configuration Guide, October 2006.

Instrumentation Laboratory GEM Premier 4000 Data Management Guide, October 2006.

Instrumentation Laboratory GEM Premier 4000 Operator's Guide, October 2006.

Instrumentation Laboratory GEM Premier 3500 Operator's Guide, October 2009.

Instrumentation Laboratory GEM Premier 3500 Training Guide, October 2009

Attachments:

No Attachments

Approval Signatures

Approver	Date
Arlene Brennan: Administrative Coordinator	11/2017
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