Name of Policy: Specimen Collection, Analysis, Integrity, and Quality Control / Quality Management Program		UT UTOLEDO HEALTH	
Policy Number: 3364-136-CBGL-06		Effective date: February 3, 2025	
Approving Officer: Medical Director, Blood Bank Program		Original effective date: 12/2003	
<b>Responsible Agent</b> : Director, Respiratory Ca Services	are		
<b>Scope</b> : The University of Toledo Medical Center Respiratory Care Services Department			
Key words: Specimen Collection, Analysis, Quality Control, Blood Gas, Procedures			
New policy proposal		Minor/technical revision of existing policy	

### Policy statement

The Blood Gas Lab will establish quality control procedures for all phases of testing.

### (A) Purpose of policy

The Quality Management and Assessment Policy is designed to monitor the processes and operations in the Pulmonary Services Blood Gas Laboratory to improve and monitor the quality of the testing. The QM policy will be reviewed annually for effectiveness. The goals of the policy are to provide high quality tests and services by:

 $\square$ 

Reaffirmation of existing policy

- detecting and preventing errors in testing processes
- reducing process variations that can cause errors

Major revision of existing policy

- improving effectiveness and efficiency of processes
- responding to customer needs in provision of services
- developing and maintaining a competent staff
- following all required regulations and accreditation standards

### (B) Procedure

#### SAFETY

A clean work area with Personal Protective Equipment and Safety Data Sheets (SDS) readily available provides a safe working environment.

#### Safety

1) When handling biological specimens, including control and calibration materials, Universal Precautions must be always followed.

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- 2) All specimens are to be considered potentially infectious.
- 3) When handling items contaminated with blood or other body fluids Universal Precautions must be followed.
  - Disposal of contaminated syringes, needles, specimen containers, and specimen testing devices should be into an appropriate biohazard container or sharps container.
  - Needles should not be recapped, bent, broken, or cut.
- 4) Care must be taken to prevent contamination of personnel and facilities. In the event of contamination, appropriate disinfectant procedures must be initiated.
  - Personnel must not eat, drink, apply cosmetics, apply lip balm, manipulate contact lenses, or smoke in areas where testing is performed.
  - All activities must follow all safety requirements as identified by The University of Toledo Medical Center.
- 5) Gloves are to be worn at all times when working with biological specimens.
  - Gloves should be changed as soon as possible when contaminated.
  - Do not re-use or wash gloves.
  - If torn or punctured, wash hands and put on a new pair.
  - After removing gloves, wash hands immediately with soap and water or an approved hand sanitizer. This should be done even with a change of gloves.
  - Change gloves between patient testing.
- 6) Leaking specimens will be rejected as contaminated since these specimens are a health hazard to the employee.
- 7) Work areas are to be clean, and the area is to be cleaned with disinfectant immediately after any spill. Hospital approved germicidal disposable wipes should be used. Wear gloves when using germicidal disposable wipes.
- 8) Instruments are to be cleaned/disinfected as needed. Wearing gloves, use hospital approved germicidal disposable wipes.
- 9) Should an exposure occur, the staff member is to report to Employee Health Services or the Emergency Department.
- 10) Disposal of specimens and specimen containers:
- Blood and body fluids- discard into biohazard bag inside a biohazard container.
- Anything (test cartridges, test tubes, etc.) contaminated by a body substance must be discarded into a properly labeled biohazard container.
- 11) Safety Data Sheets (SDS) are available for reagents/supplies.

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#### **Patient Considerations**

The patient's ventilation and oxygen delivery should be stable during specimen collection.

Arterial blood gas puncture specimen should be performed in compliance with Pulmonary Services Department Policy 3364-136-08-06. As stated in the policy, the needle must be disposed of properly and replaced with a hospital approved filter device that accompanies the puncture syringe. No needles are to be sent to the lab.

#### PRE-ANALYTICAL

Specimen Collection

To be acceptable for testing:

- 1. All testing must have a documented physician's order.
  - In certain instances, procedures contain standard orders for testing, for example, in OR, blood gas testing is a standard of care.
- 2. When obtaining specimens, verification of patient name and medical record number (inpatients) or date of birth (outpatients) is necessary to ensure proper identification of the sample.
  - Two identifiers must be utilized.
  - Inpatients: the testing personnel should verify the patient's name and medical record number by checking the patient's hospital armband against, for example, but not limited to, the patient's master ID card.
  - Outpatients: armbands are not used; therefore, testing personnel should ask the patient his name and date of birth.
- 3. Collection Procedure
  - Confirm order for arterial blood gas
  - Obtain appropriate equipment and supplies
  - Introduces self to patient/family
  - Washes hands and uses Standard Precautions
  - Selects appropriate puncture site
  - Performs Allen's test (for radial artery puncture only) to assure collateral circulation
  - Aseptically prepares the puncture site by thoroughly cleaning site
  - Stabilizes area and properly positions puncture site
  - Carefully punctures radial artery (using approximately a 45-degree angle)
  - Verifies pulsatile blood flow and obtains adequate volume of arterial blood
  - Carefully removes needle from puncture site and applies pressure to sit for five (5) minutes minimum
  - Expels all air from sample
  - Applies needle protection device, removes the device, and seals the syringe
  - Patient identification label is appropriately applied to sample at bedside
  - Blood sample is placed in ice (if not analyzed within 15 minutes) and placed into biohazard bag
  - Re-evaluates puncture site to verify the absence of bleeding and hematoma formation
  - Notes time, puncture site, FIO2, oxygen device, temperature, and ventilator settings as appropriate

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- Takes appropriate action for adverse response and notifies appropriate personnel
- Appropriately processes all used supplies and disposes of sharps in correct containers
- Notifies appropriate personnel of test results and critical values and documents notification
- 4. Specimens must be labeled as follows:
  - Patient identification sticker which includes patient name, identification number, date, collection time, initials of the person that obtained the sample.
  - For patients on oxygen or mechanical ventilation the inspired oxygen or the ventilator settings must be included.
- 5. Specimen rejection criteria:
  - Unlabeled specimen
  - Mislabeled specimen
  - Needle still attached to syringe
  - Clotted sample
  - Insufficient sample
- 6. Patient Identification will be Name and Medical Record Number or patient encounter number. The test accession number is obtained prior to analyzing the specimen.
- 7. Specimen condition must be assessed.
  - Arterial, mixed venous, venous, or pleural fluid can be analyzed in the blood gas laboratory.
  - Sample minimum volume is 150 microliters collected in a heparinized syringe or

Lithium Heparin vacutainer tube.

- Sample should have all air bubbles removed, and sample container should be placed in ice bath if not analyzed within 15 minutes. This is done to slow cell respiration.
- Samples should be analyzed within one hour of its collection.
- 8. If a specimen is rejected for testing, document the specimen is rejected and why, the patient data, and tests ordered on the error variance log sheet.
- 9. Vendor notifications regarding defects or issues with supplies such as product recalls or market withdrawals will be retained, and follow-up will be documented. Action will be taken on those that have the potential to affect testing results or laboratory services.

#### Procedures

1. Any new lab procedure/method must be validated prior to being used for patient testing. Each of the following specifications, when appropriate, is to be documented:

- Analytic accuracy is the agreement between test result and the "true" result. This can be accomplished by either:
  - ✓ patient comparisons/correlations between the new method and "reference" method or
  - $\checkmark$  comparisons of results using the new method with certified reference materials (recovery)
- Precision will be established by repeat measurement of samples at varying concentrations.
- Analytic sensitivity (lower detection limit) will be established by using linearity standards, old CAP surveys, calibrators, or controls, or making dilutions of a patient specimen. This is

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usually established or verified by analyzing the "Reportable Range" or Analytical Measurement Range.

- Specificity information concerning interfering substances should be gathered from product labeling and the literature covering lipemia, hemolysis, icterus, anticoagulants, antibiotics, treatments, disease states, etc.
- Reportable Range is to be verified or established for each analytical procedure before implementation. The analytical measurement range (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution or concentration.
  - ✓ The AMR is the range of analyte values that a method can directly measure on the sample without any dilution, concentration, or other pretreatment that is not part of the usual assay process. Records of establishment/verification of ranges are on file.
- Reference Ranges/Intervals (normal values) should be verified/established for each analyte and specimen source. Twenty healthy individual's samples can be tested and if no more than two (2) results fall outside the proposed reference interval, that interval can be considered verified for the population studied. If a formal reference interval study is not possible or practical, published literature references and manufacturer's manuals and package inserts can be used.
  - Records of reference range studies or records of verification of manufacturer's stated range when reference range study is not practical or other methods approved by the laboratory director will be on file.
  - ✓ Reference ranges will be evaluated when a new analyte is introduced to the test menu, when there is a change of methodology and a change in population.
- 1. Any new or revised procedure/policy must be approved prior to implementation and reviewed, initialed/signed by the Lab Director, or designee, before being placed into use and in the procedure manuals.
  - Procedures may be edited for minor clarifications by the authority of the Laboratory Director or designee. Any such edits made must be dated and initialed.
  - There is a summary statement, signed by the laboratory director documenting evaluation of validation/verification studies and approval of each test for clinical use. The summary must include the following statement: "The validation data has been reviewed for accuracy, precision, reportable range, and reference range and the performance of the method is considered acceptable for patient testing."
- 2. The Quality Management and Assessment Policy and Laboratory Personnel Evaluation Roster form will be reviewed annually. All other policies and procedures will be reviewed at least every two (2) years by the Lab Director, or Technical Consultant designee.
- 3. Should there be a change in directorship, the new director will review and re-approve all procedures/policies within a reasonable length of time.
- 4. Any new or revised procedure should be reviewed, initialed, and dated by staff performing testing.
- 5. A copy of discontinued or revised procedures will be retained for a minimum of two (2) years, recording the initial date of use, and discontinued or revised date.
- 6. Procedure manuals should be available to all staff.

Personnel

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- 1. The laboratory director is responsible for technical and scientific oversight of blood gas testing. At UTMC the laboratory director is a pathologist. The director at UTMC has delegated the performance of competency assessment to qualified technical consultants.
- 2. Technical consultants (TC) are responsible for competency assessments for personnel performing blood gas testing which is non-waived or moderately complex testing and arterial punctures.
  - Technical consultants must have a bachelor's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution with at least two (2) years of training and/or experience in non-waived testing.
- 3. Personnel performing Blood Gas testing (non-waived) must be listed on the Laboratory Personnel Evaluation Roster form. There must be documentation that demonstrates personnel meet the required educational qualifications to be testing personnel. At UTMC, transcripts are available on file for testing personnel.

#### Competency Assessment

- 1. Competency testing of personnel performing non-waived blood gas testing and arterial punctures must be assessed by a technical consultant prior to starting patient testing and to reporting patient results.
- 2. Competency must be assessed as follows:
- New employees prior to patient testing will receive initial training on the blood gas analyzer and specimen collection
- During the first year of an employee's duties, competency must be assessed at least semiannually.
- After an employee has performed their duties for one year, competency must be assessed at least annually.
- Should there be a change in instrumentation or methodology, competency assessment will be performed prior to the performance of patient testing.
  - a. Retraining and reassessment of competency must also occur when problems with an employee's performance is identified.
- 3. Competency assessment records for non-waived blood gas testing must include all six (6) elements as described below for each employee:
  - a) Direct observation of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing, and testing.
  - b) Monitoring the recording and reporting of test results including critical results.
  - c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records.
  - d) Direct observation of performance of instrument maintenance and function checks.
  - e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

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- f) Evaluation of problem-solving skills. Assessment of problem-solving skills can be achieved through communication with the staff members when issues arise that require critical thinking and with a written exam.
- 4. Many of the elements of competency assessment may be performed during routine review of personnel throughout the year.
- 5. Records of competency assessments will be kept in the Pulmonary Services department in the employee files.

### ANALYTICAL

#### Analysis Procedure

- 1. Expel all air if present.
- 2. Mix the sample thoroughly. Use quick inversion to mix sample for  $\geq 30$  seconds.
- 3. Push out a few drops of the sample onto a gauze pad to ensure there is no clot in the syringe tip.
- 4. Results will communicate with the EMR
- 5. Verify results and report critical values to the licensed provider in the appropriate unit, then release information into the system.
- 6. For pleural fluid specimens, the same analysis procedure is performed.

#### Reagents

- 1. GEM Premier 5000 reagents include the Cartridge pack and Performance Valuation Product (PVP))
- 2. **NO** reagents are to be used beyond the expiration date. Reagents used for patient testing must be within their expiration date. DO NOT use outdated reagents.
- 3. Reagents used for lab testing must be handled and stored according to the manufacturer's instructions as stated in each procedure.
- 4. Monitoring of room and refrigerator temperature is done with an automated temperature monitoring system. Temperature monitoring is necessary to maintain the integrity of reagents.
  - With this system, when any temperatures are out of range, a designated person will be notified, and they can document their response to the alarm.
    - ✓ If the temperature adjustment fails to bring the temperature within acceptable range, contact Facilities Maintenance.
    - $\checkmark$  Documentation of any problem, action, and resolution is necessary.
  - If the refrigerator temperature is obviously not cooling when attempting to read the temperature:
    - $\checkmark$  Assess the stability of the reagents inside.
    - ✓ Discard reagents that have exceeded the manufacturer's guidelines for storage and stability.

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- ✓ Identify an alternate refrigerator for storage of reagents that are found to be acceptable to retain.
- ✓ Notify Facilities Maintenance.
- $\checkmark$  Documentation of any problem, action, and resolution is necessary.

### Quality Control

Quality Control consists of an internal program, an external program.

- 1. Internal quality control program uses commercially prepared solutions utilized on a routine basis to monitor the accuracy and precision of a method.
  - The GEM Premier 5000 system is designed to allow patient testing only when internal control testing is within acceptable quality ranges.
  - Intelligent Quality Management 2 (iQM2) is used as the quality control and assessment system for the GEM 5000. iQM2 is an active quality process control program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, automatic correction of the system, and automatic documentation of all corrective actions, replacing the use of external quality controls.
  - Every GEM PAK automatically runs through an AutoPAK Validation process, utilizing two
    independent NIST or other primary standard-traceable solutions. Additionally, every GEM
    PAK for the GEM Premier 5000 system automatically runs five levels of NIST or other
    primary standard-traceable Process Control Solutions (PCSs), analyzed at different intervals
    throughout onboard use-life after every patient sample every 30 minutes, every four (4)
    hours, every 12 hours, and every 24 hours.
  - More specifically:
    - ✓ Five levels of PCSs monitor sensor performance at all Medical Decisions Levels.
    - $\checkmark$  QC is performed through the entire analytical pathway from sample probe to waste bag.
    - ✓ iQM2 provides 5 continuous quality checks (System, Sensor, IntraSpect, Pattern Recognition and PCS Stability) and real-time quality checks before, during and after every patient sample.
    - ✓ iQM2 detects sample errors in minutes vs hours with traditional QC methods, and hundreds of PCSs are performed each day, exceeding CMS external QC requirements.
    - ✓ iQM2 automatically detects, corrects, and documents sample errors and corresponding corrective actions(s).
- 2. External quality control program uses proficiency testing that provides a peer comparison to assess reliability of a method and resolve problems not detected by the internal quality control program.
  - Proficiency testing programs or CAP approved alternative proficiency testing (PT) programs for non-waived testing will be subscribed to as required by the College of American Pathologists (CAP) for the patient testing performed.
  - If any non-waived tests are performed that CAP does not require PT be done or no commercial PT is available, an alternative performance assessment system for determining the reliability of analytic testing will be utilized at least semiannually.
  - Under no circumstances will the PT specimens be treated any differently than any patient specimen.

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- PT samples are integrated within the routine laboratory workload with those samples analyzed by personnel who routinely test patient samples using the same primary method as for patient samples.
- PT samples must be rotated between all testing personnel
- Duplicate or repetitive analysis of PT samples is acceptable only if patient specimens are routinely analyzed in the same manner.
- PT samples should not be tested on more than 1 instrument unless that is how patient specimens are tested. When two or more instruments are used for testing, the samples should be rotated between them.
- PT specimens are not to be referred to other laboratories and are not accepted from other labs for analysis.
- There is to be no inter-laboratory communication about PT specimens until after the deadline for data submission.
- The PT specimens are to be stored, prepared, analyzed, and reported in accordance with the instructions supplied by the PT agency.
- Verification of storage and any special handling should be performed upon receipt of PT samples.
- Results or printouts should be kept with the PT result form.
- The attestation page will be physically signed by the Laboratory Director or designee and each staff member who runs an assay.
- PT results are entered on-line to the PT agency before the due date.
- When the results are received, all results, including ungraded, educational, and results that were intended to be graded but were not, are reviewed for acceptability by the Lab Director or qualified designee, signed and dated with review date. The reviewed results are to be kept in the year appropriate binder.
- If an ungraded exception code is present, the "all participant" statistics are reviewed for any explanation.
- All PT data will be retained for at least two (2) years.
- If any PT result is unacceptable, a Proficiency Testing Corrective Action form is to be filled out documenting the actions taken, resolution, and how to prevent a recurrence. The form is to be submitted with the PT result report to the Laboratory Director or qualified designee for review, signature of review, and date.
- The Proficiency Testing corrective action form is to be kept with the result form in the binder.
- Actions that can be taken when investigating unacceptable results:
  - ✓ Check for clerical errors. If transcription was correct, continue investigation.
  - ✓ If original PT sample is available repeat the failed test. If the repeat is not acceptable, further investigation is necessary.
  - ✓ Verify lot numbers of reagents originally used and at the time of investigation. Were any problems documented for the lot number used for original test?
  - ✓ Review procedure to verify it was followed correctly.
  - ✓ Was the correct sample used for the assigned tests?
  - ✓ If appropriate, check instrument history. Has routine maintenance been performed accordingly? Was there an instrument failure around the time of the original PT testing?
- The unacceptable assay will be noted on the PT evaluation form, with all actions and resolutions taken to evaluate unacceptable results documented on the Proficiency Testing Corrective Action form.
- If CAP has instructed the laboratory to cease patient testing for an analyte due to repeat unsuccessful proficiency testing, laboratory records must show that no patient results were

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released until after the laboratory received approval from CAP to resume patient testing. Documentation must exist that notification about suspended testing was communicated to staff and physicians.

#### Calibration using PVP

Calibration on the GEM 5000 Premier is the measurement of calibration materials for verification of correct method calibration, and to establish Analytical Measurement Range (AMR) validation. Calibration must be performed following manufacturer's instructions, and the records are reviewed for acceptability.

- 1. Calibration frequency for each individual assay is to be included in each written procedure, where appropriate, and will be done:
  - As recommended by manufacturer
  - At least every six (6) months
  - When indicated by quality control data
  - Following major instrument repair/service
  - If a change in a reagent lot number will affect the accuracy of patient test results and the ranges used to report patient test data or the control value
- 2. The Analytical Measurement Range (AMR) is to be verified at least every six (6) months and following changes in major system components or lot numbers of analytically critical reagents to verify the range of values the method can directly measure through one of the following:
  - A purchased product, standard or a patient sample will be used. Product instructions must be followed to determine acceptable limits.
  - If the results are not acceptable, repeat the testing. Recalibration may be necessary. If repeat testing is still not acceptable, troubleshooting is necessary.

#### Instrument and Equipment Maintenance/Function Checks

- 1. Manufacturer's instructions for instrument and equipment maintenance and function checks will be followed and performed at least as frequent as specified by the manufacturer. Instructions are included in each written procedure. Documentation will be available.
- 2. The performance of non-waived instruments and equipment is verified upon installation and after repair or reconditioning to ensure that they run according to expectations. Records are available.
- 3. Each written procedure will include start-up, operation and shutdown of instruments and equipment if applicable.
- 4. Maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or qualified designee.

#### Comparability of Instrument/Method

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Correlation studies for non-waived testing will be performed twice a year with other methods and instruments being used in the institution for testing the same analytes. Acceptability criteria is listed in the Method/Instrument Comparison policy.

### **POST-ANALYTICAL**

#### Result Reporting

- 1. Analyzer printouts are for reference only and are not part of the patient's medical record.
- 2. Patient results will be reviewed when testing is performed by the testing personnel. Results should be interpreted with respect to the patient's condition and clinical circumstances. Those results that do not agree with the expected values should be repeated and further evaluated, if indicated.
- 3. The analytical measurement range (AMR) for each analyte are posted in each blood gas room for reference.
- 4. Results that fall outside the limits of the Reportable Range will be reviewed and reanalyzed if necessary. Results outside the Reportable Range are reported as < (less than) or > (greater than) symbol.
- 5. Physicians or other clinical personnel responsible for patient care will be notified immediately when results meet critical limits. Documentation of notification or attempts to notify the appropriate person will be done by comment in result entry.
- 6. Patient test results should be documented promptly following the completion of the test.
- 7. Patient test results are interfaced with the electronic medical record (EMR).
- 8. Results from the GEM are reviewed in the EMR by staff before release to the patient's medical record.
- 9. Reference (normal) ranges will be included, when appropriate, with all final results.

Any significant delays in reporting results should be documented. The ordering clinician should be notified of delay and the contact documented.

For reporting purposes, all pH values are rounded off to the nearest 100<sup>th</sup>, sodium (Na) values are rounded off to the nearest whole number, potassium (K) values are rounded off to the nearest tenth, and ionized calcium rounded off and reported to the nearest 100<sup>th</sup>.

#### **Report Format/Content Review**

The laboratory director reviews and approves, at least every two years, the content and format of the laboratory patient reports to ensure they effectively communicate the patient test results and meet the needs of the hospital and medical staff.

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Reports from each interface and its corresponding report from the EMR are printed.

The reports are reviewed by the Point of Care Coordinator, or designee and signed off as acceptable or unacceptable. Anything unacceptable is corrected.

A report view will also occur at the time of implementation of a new report format, a new test or new reporting mechanism, or at the time of a major system change.

Reportable Ranges for GEM 5000

The reportable range for a parameter is the range where software default limits have been configured. Analytes with measured values outside the Reportable Range are reported with a > (greater than) or < (less than) symbol. Incalculable will be displayed for results that are outside the measuring capability of the analyzer.

Reference Ranges

Arterial	
pН	7.35 - 7.45

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pCO2 mmHg	35 - 45	
pO2 mmHg	83 - 108	
Na <sup>+ 1-2</sup> mmol/L	136 - 146	
K <sup>+1</sup> mmol/L	3.4 - 5.2	
HCO <sub>3</sub> <sup>-</sup> mEq/L	21 - 28	
ICA <sup>++</sup> mmol/L	1.13 – 1.32	
THb g/dL	12.0 - 16.3	
O2Sat <sup>*</sup> %	94.0 - 100.0	
O2Hb %	94.0 - 97.0	
СОНЬ %	0.0 - 1.5	
MetHb %	0.0 - 1.5	
HHB %	0.0 - 5.0	
Venous		
pН	7.31 - 7.41	
pCO2 mmHg	40 - 50	
pO2 mmHg	35 - 45	
References:		
Hess, D., Respiratory Care Principles and Practice, 2 <sup>nd</sup> Edition, ISBN#: 978-0-7637-6003-8.		

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<sup>1</sup>Plasma <sup>2</sup> Serum \*O2 Sat is a derived parameter calculated from measured CO-Oximetry results

\*\* BE (Base Excess) is a derived parameter

#### **Instrument Maintenance**

The lab personnel will perform all services and maintenance according to the Werfen schedule for the GEM 5000 analyzer, including monitoring and documentation of blood gas lab room temperature. The therapist assigned to each patient care unit which houses a blood gas analyzer, will monitor room temperature and any QC alerts daily. The Blood Gas Lab Director or designee will review and sign off on these actions as indicated by QC results. All repairs and maintenance must be documented. Maintenance reports will be reviewed monthly and initialed by the Lab Director or designee. All new instruments will be set up according to manufacturer and CLIA guidelines during installation.

Approved by:	Policies Superseded by This Policy:
/s/	• $n/a$
	Initial effective date: 12/2003
Melissa Kukiela BSRC, RRT	
Director, Respiratory Care Services	Review/Revision Date:
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2/3/2025	11/17/2005 12/06/2006
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Date	02/25/2008
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Medical Director	03/01/2023
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