Name of Policy: **Specimen Collection, Analysis, Integrity and Quality Control / Quality Management Program ROTEM Sigma** **Policy Number**: 3364-136-CBGL-12 **Approving Officer**: Medical Director, Blood Bank Program **Responsible Agent**: Director, Respiratory Care Services **Scope**: The University of Toledo Medical Center Respiratory Care Services Department	UTOLEDO HEALTH **Effective date:** **Original effective date**:
Key words: ROTEM Sigma, Blood Gas, Lab, Quality Control, Diagnostics	

☒	New policy proposal	☐	Minor/technical revision of existing policy
☐	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) Policy statement

The Blood Gas Lab will establish quality control procedures for all phases of testing. The ROTEM sigma Thromboelastometry system is designed for in vitro diagnostics in the Point of Care (POC) (near-patient test) or in laboratory settings. The system is intended to provide a semi-quantitative indication of the coagulation state of a blood sample. The system records the kinetic changes in a citrated whole blood sample during clot formation as well as when the sample clot retracts and/or lyses. Different parameters are measured and reported for this purpose. The graphical presentation reflects the various physiological results, which describe the interaction between coagulation factors and inhibitors, fibrinogen, platelets, and the fibrinolysis system. Additionally, the effect of certain drugs influencing coagulation, particularly some anticoagulants (e.g. Heparin), can be detected.

(B) Purpose of policy

The Quality Management and Assessment Policy is designed to monitor the processes and operations in the Respiratory Care 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:

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

(C) Procedure

SAFETY

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

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

Device Considerations

- Adhere to the following instructions for the safe use of the ROTEM sigma:
- Do not use the equipment if it is not working properly or damaged.
- Do not leave the equipment unattended if it is used near children or disabled persons.
- Use the equipment only for the purposes described in this user manual (Chapter 2.2).
- Liquids may damage the internal components of the equipment. Do not spill liquids over or into the ROTEM system.
- Do not immerse the equipment in water or other liquids.
- Only qualified service personnel may access internal components of the ROTEM system.
- If safe operation of the ROTEM system cannot be guaranteed, discontinue use of the system and prevent further use.
- Do not let the equipment or its power cable encounter surfaces that are too warm to touch.
- Do not cover air openings nor place equipment on a soft surface which might block them. Keep air openings free from lint, hair, dust etc.
- Do not place anything on top of the equipment, except the accessories recommended by the manufacturer.
- Unless specified in the user manual, do not stuff or put anything into the openings, tubes or couplings of the
  equipment.
- Do not use the ROTEM sigma near or in flammable or explosive atmospheres.
- The equipment is designed for indoor use only.
- Only software explicitly supplied by Tem Innovations GmbH may be installed on the ROTEM sigma system.
- Do not drop the equipment or expose to physical shocks.
- Only use qualified ROTEM sigma system material.

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 ROTEM sigma
   - Obtain appropriate equipment and supplies

- Introduces self to patient/family
- Washes hands and uses Standard Precautions
- Collect the blood sample carefully according to the references below:
  - CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Seventh Edition.
  - CLSI document GP41-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.
  - CLSI. Procedures for the Collection of Arterial Blood Specimens; Approved
- Takes appropriate action for adverse response and notifies appropriate personnel
- Appropriately processes all used supplies and disposes of sharps in correct containers

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.
7. Specimen condition must be assessed. The following blood sample tubes (3.2% buffered sodium citrate) have been tested on the ROTEM sigma:
   - BD Vacutainer®: 2.7, 4.5 mL
   - Greiner Bio-One Vacuette®: 3.5 mL, 5 mL
   - Sarstedt S-Monovette®: 3 mL, 4.3 mL (only in combination with Vial Adapter ROTEM sigma, REF 415502 or Sarstedt adapter REF 14.1216)
   - Kabe Primavette: 2.9 mL (only in combination with Sarstedt adapter REF 14.1216)
   - Any larger volume sample tube can also be used.
   - Ensure that the sample tubes are properly filled.
   - Do not shake samples.
   - Do not roll the sample tube.
   - Samples should be stored at room temperature.
   - Do not store samples on ice.
   - Avoid touching the needle in the cartridge sample position.
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
  - ✓ 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 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.

2. Any new or revised procedure/policy must be approved prior to implementation and reviewed, initialed/signed by the Laboratory Director, or designee, before being placed into use and in the procedure manuals.
   1. 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.
   2. 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."
3. 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 Laboratory Director, or Technical Consultant designee.
4. Should there be a change in directorship, the new director will review and re-approve all procedures/policies within a reasonable length of time.
5. Any new or revised procedure should be reviewed, initialed, and dated by staff performing testing.
6. 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.
7. Procedure manuals should be available to all staff.

Personnel

1. The laboratory director is responsible for technical and scientific oversight of viscoelastic assay 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 viscoelastic assay testing which is non-waived or moderately complex testing.
   - 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 viscoelastic assay 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 viscoelastic assay testing 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 ROTEM sigma 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.
   - Retraining and reassessment of competency must also occur when problems with an employee's performance is identified.
3. Competency assessment records for non-waived viscoelastic assay 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.
   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 Respiratory Care department in the employee files.

ANALYTICAL

Analysis Procedure:

1. Ensure the cartridge from the previous sample/measurement has been removed.
2. Locate the log-in screen.
3. Touch the screen if the screen saver is active.
4. Select user.
5. Enter password.
6. Measurement:

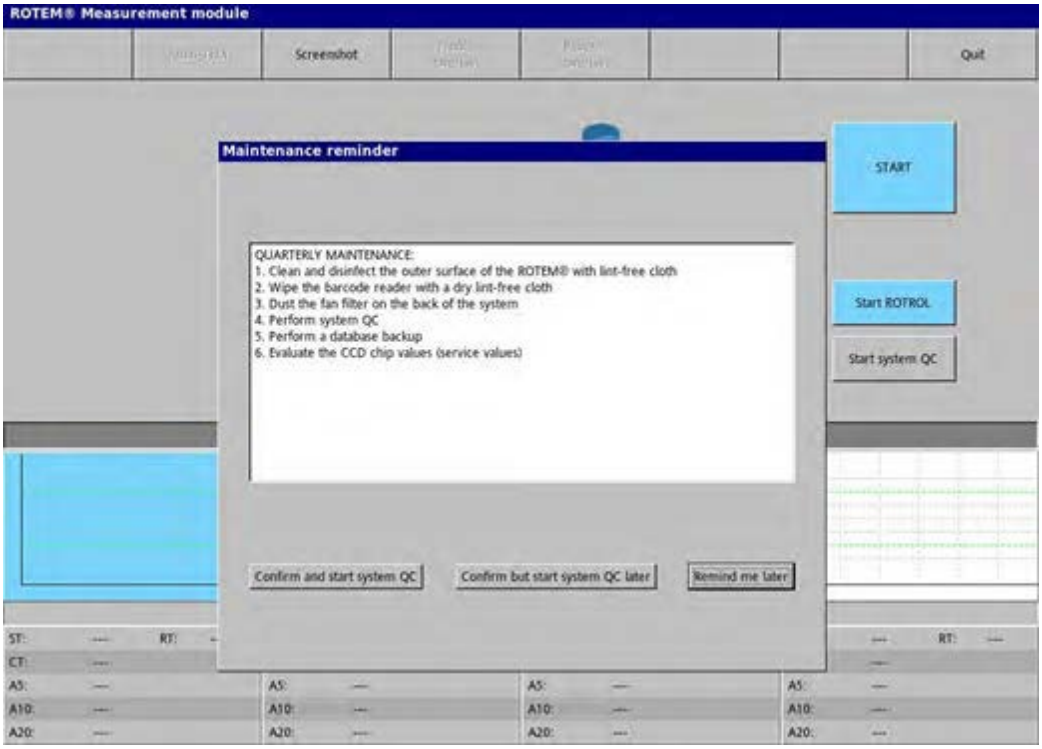

Figure 6-1: Details of the measurement start screen

The color of the status (see number 4 Figure 7-3) line below each channel provides information on the channel status.

Color	Status
Grey	Channel ready to use
Blue	Channel not ready, initialization may be active
Green	Measurement is running
Yellow	Warning message during measurement
Red	Error, measurement is stopped

Table 6-1: Colors of the status line

- Select **START**.
- Follow the menu navigation.
- Confirm the patient data by scanning the barcode on the patient sticker or manual entry.
- Mandatory fields are displayed in **BLUE**.

- Do not use special characters when entering patient data.

7. Graphics of measurement results:
   - Only numerical CT values can be used for interpretation.
   - The TEMogram CT must not be used for clinical interpretation.
8. Sample warning during measurement:
   - The **WARNING** button is hidden during measurement and will only appear if a system error occurs.
   - Touch the **WARNING** button and note the error caption.
   - If the TEMogram is plausible, continue measurement (press **IGNORE**). If not, cancel the measurement (press **STOP**). In case of uncertainty, stop and repeat the measurement.
   - If the error is reproducible with a follow-up sample, contact the service provider.
9. Stopping a measurement:
   - A patient measurement will automatically stop after two (2) hours.
   - A QC measurement will automatically stop after 1.5 hours.
   - A single channel may be manually stopped by selecting **STOP CHANNEL.**

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.
     - ✓ Documentation of any problem, action, and resolution is necessary.
   - If the refrigerator temperature is obviously not cooling when attempting to read the temperature:
     - ✓ Assess the stability of the reagents inside.
     - ✓ Discard reagents that have exceeded the manufacturer's guidelines for storage and stability.
     - ✓ Identify an alternate refrigerator for storage of reagents that are found to be acceptable to retain.
     - ✓ Notify Facilities Maintenance.
     - ✓ Documentation of any problem, action, and resolution is necessary.

Quality Control

Quality Control consists of ROTEM sigma system (instrument, cartridges and control to ensure that the system functions as intended. This includes internal system quality control features for instrument and cartridge) as well as the ROTEM sigma system QC (sQC) cartridge for more extensive system functionality testing.

1. Cartridges and controls are manufactured with in-process controls to ensure lot-to-lot reproducibility and performance. Production samples are tested and confirmed to be working to specifications before each lot is released.

2. The instrument continuously checks the functions of the system. Channel status information is displayed automatically if a self-test failure is detected. If the impacted component is critical for sample measurement, system operation is blocked automatically. Additionally, the AD Module Service Values are a measure of the quality of the analytical system and are checked during quarterly maintenance.
3. 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.
    - 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 Laboratory Director or 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. Document any issues with the resulting. Review procedure to verify it was followed correctly.
  - ✓ Ensure correct sample was utilized. If appropriate, check instrument history Ensure routine maintenance was performed. Verify the instrument is/was in good working order.
- 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 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.
- The ROTEM sigma system QC cartridge is available for more extensive system functionality testing. It should be run in accordance with regulations.

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

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 ROTEM 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.

Report Format/Content Review

The laboratory director reviews and approves, at least every two (2) 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.

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 ROTEM Sigma

The reportable range for a parameter is the range where software default limits have been configured. 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

The ROTEM sigma supports the following reportable ranges. Values above or below the reportable range of the ROTEM sigma system are displayed as shown in Table 4-5.

Test	Parameter	Low	High	Display Within Range	Display Outside of Range	
INTEM C	CT (s)	123	365	Actual value	< 123	> 365
	A5 (mm)	11	66	Actual value	< 11	> 66
EXTEM C	A10 (mm)	16	74	Actual value	< 16	> 74
	A20 (mm)	21	78	Actual value	< 21	> 78
FIBTEM C	MCF (mm)	24	79	Actual value	< 24	> 79
	LI60 (%)	0	100	Actual value	**	
	ML* (%)	0	100	Actual value	**	
	CT (s)	45	172	Actual value	< 45	> 172
	A5 (mm)	13	69	Actual value	< 13	> 69
	A10 (mm)	18	77	Actual value	< 18	> 77
	A20 (mm)	23	81	Actual value	< 23	> 81
	MCF (mm)	25	82	Actual value	< 25	>82
	LI60 (%)	0	100	Actual value	**	
	ML* (%)	0	100	Actual value	**	
	A5 (mm)	2	33	Actual value	< 2	> 33
	A10 (mm)	2	36	Actual value	< 2	> 36
	A20 (mm)	2	38	Actual value	< 2	> 38
	MCF (mm)	2	41	Actual value	< 2	> 41
HEPTEM C	CT (s)	122	376	Actual value	< 122	> 376
	A5 (mm)	10	59	Actual value	< 10	> 59
	A10 (mm)	15	68	Actual value	< 15	> 68
	A20 (mm)	20	73	Actual value	< 20	> 73
	MCF (mm)	24	75	Actual value	< 24	> 75

Table 4-5: Reportable Ranges
P/N

Instrument Maintenance

The lab personnel will perform all services and maintenance according to the Werfen schedule for the ROTEM sigma analyzer, including monitoring and documentation of blood gas lab room temperature. The Respiratory Care department or designee 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.

(D) References

ROTEM sigma user manual REV. 00 August 2022

Approved by: _____ Melissa Kukiela BSRC, RRT Director, Respiratory Care Services _____ Date _____ Lauren Stanoszek, MD Medical Director _____ Date *Review/Revision Completed by:* *Director, Respiratory Care*	**Policies Superseded by This Policy:** • *n/a* Initial effective date: Review/Revision Date: Next review date: