# PROCEDURE
# Corewell Health East - ROTEM delta - Trenton and Farmington Hills

**This Procedure is Applicable to the following Corewell Health sites:**
Corewell Health Farmington Hills Hospital, Corewell Health Trenton Hospital

**Applicability Limited to:** Within Farmington Hills, Farmington Hills only.

**Reference #:** 34390

**Version #:** 2

**Effective Date:** 10/09/2025

**Functional Area:** Clinical Operations, Laboratory

**Lab Department Area:** Lab - Hematology

## 1. Purpose and Objective

The purpose of this procedure is to provide guidance to the staff regarding the operation of the ROTEM *delta.*

## 2. Principle

A. The ROTEM system is a further development of classical thromboelastography developed by Hartert. The ROTEM delta Thromboelastography systems are designed for in vitro diagnostics in hospital laboratories. The system is intended to provide a quantitative and qualitative indication of the coagulation state of a blood sample. The system records kinetic changes in a sample of citrated whole blood during clot formation, as well as when the sample clot retracts and/or lyses (breaks apart). Different parameters of the clotting are measured, analyzed, monitored, and charted for this purpose. The graphical presentation reflects the various physiological results, which describe the interaction between components like coagulation factors and inhibitors, fibrinogen, thrombocytes, and the fibrinolysis system. Additionally, the effect of certain drugs influencing hemostasis, in particular anticoagulants, can be detected.

1. The patented ROTEM technology is based on a fixed cylindrical cup and a permanently oscillating vertical axis. The axis is supported by a high precision ball bearing and oscillates to the left and to the right through an angle of 4.75°. The rotation of the axis is driven by a motor that is connected to the axis via an elastic spring. For the measurement, a disposable plastic pin with 6mm diameter is placed firmly on the axis and the blood sample is filled into a disposable 8mm diameter cup and is then lifted onto the measurement channel. Hence, the plastic pin is immersed into the blood sample.

B. The rotation is detected optically via a motor plate at the upper end of the axis, a diode as light source and a light sensitive sensor (CCD chip). If no clotting takes place, the movement is not obstructed. When a clot is formed and attaches to itself between pin and cup surfaces, the movement is obstructed.

C. The result is a balance between the spring tension and the tension of the clot. As the clot becomes firmer, the rotational amplitude of the axis is reduced. The results of the measurement are interpreted with special software.

## 3. Responsibility

Entities will reference associated Documentation contained within this document as applicable
Printouts of this document may be out of date and should be considered uncontrolled.

Personnel who have completed the competency requirements will perform this testing.

**4. Definitions**

A. Clotting Time, CT (seconds): Time from beginning of the test by adding the clotting activator until the time when the movement amplitude of 2mm is achieved.
B. Clot Formation Time, CFT (seconds): The CFT is the time between 2mm amplitude and 20 mm amplitude of the clotting signal.
C. Alpha Angle, (degree): The Alpha angle is defined as the angle between the middle axis and the tangent to the clotting curve through that 2mm amplitude point. It describes the kinetic of clotting.
D. Maximum Clot Firmness, MCF (mm): The MCF is the measure for the firmness of the clot and therefore clot quality. It is the maximum amplitude that is reached before dissolution of the clot by fibrinolysis and the clot firmness falls again.
E. Amplitude 10, (mm): The A10 represents the clot firmness. The A10 is the amplitude after 10 minutes after CT.
F. Amplitude 20, (mm): The A20 represents the clot firmness. The A20 is the amplitude after 20 minutes after CT.
G. Lysis Index at 30 min (LI30) and the related parameter (%): The LI30 value represents the fibrinolysis 30 min after CT. It is the relation of the amplitude to the maximum clot firmness (% remaining clot firmness). The LI60 parameter describes the according remaining clot firmness 60 min after CT.
H. Maximum Lysis, ML (%): ML describes the degree of fibrinolysis relative to maximum clot firmness (MCF) achieved during the measurement (% clot firmness lost).
I. Lysis Onset Time, LOT (s): Time span from CT to the start of significant lysis in seconds (s). Significant lysis is defined as a decrease of the amplitude of 15% as compared to the MCF.
J. Measurement cell rod (MC rod): Rod used to fully seat the cups used for testing into the measurement cell holders.

**5. Specimen**

A. Patient Preparation
    1. No special preparation is required.
B. Type – Whole Blood
    1. Containers: B-D blue top tube containing 0.5 mL of 0.105 molar 3.2% buffered Sodium citrate (4.5 mL draw).
    2. Volume: B-D blue top tubes require an exact blood: anticoagulant ratio of 9:1. Therefore any blue top tube is required to be filled exactly to the blue line on the tube.
C. Collection: Collect specimen using standard venipuncture technique. The specimen should be collected with a minimum of trauma. Invert tube 8 times to gently mix blood with anticoagulant.
D. Handling and Storage Instructions:
    1. Whole blood samples are required. DO NOT SPIN DOWN! If the specimen is spun down, a new full blue top tube must be drawn. This tube is for the ROTEM ONLY, no other testing can be done on this specimen.
    2. Whole blood MUST be tested within 4 hours of collection.
    3. Specimen must be warmed to 37°C for a minimum of 5 – 10 minutes before testing in sample preheating station.
    4. Cautions: Do not shake specimens.
        a. Do not roll specimen container.
        b. Do not expose specimen to cold temperatures
        c. Never store specimens on ice.
E. Causes for rejection:
    1. Improperly identified specimen.
    2. Clotted specimen.
    3. Inadequate volume.
    4. Specimens that have been spun down.
    5. Specimen > 4 hours old.

6. Specimen stored on ice or refrigerated.
7. Specimens sent through the pneumatic tube system.
8. Ordering physician not on approved ordering list. For the Trenton Campus laboratory only.

F. Specimen Identification
1. All specimens should be labeled with the patient's name, identification number, time of collection, and initials of blood drawer.

G. Handling Conditions
1. CAUTION: General standard precautions apply when testing. Gloves and a lab coat must be worn when handling and opening specimens.

**6. Reagent/Equipment Needed**

A. Storage and Stability
1. Store reagents in refrigerator at 2 – 8°C when not in use.
2. Reagents must be mixed gently but thoroughly after withdrawal from the refrigerator and prior to each use.
3. During the workday, reagents may be kept at room temperature, but vials must be closed tightly immediately after each use to avoid evaporation.
4. Unopened reagents are stable until the expiration date indicated on the label.
5. Opened vials must be labeled with new open expiration date and used within the stability after opening. See Table 1 below.

B. Preparation
1. All reagents except HEPTEM are Ready for use. No reconstitution is necessary.
2. Mix all reagents gently but thoroughly before use.
3. Tap top of reagent caps to ensure that all reagent is in the bottle.
4. Write the date of opening and expiration on bottles.
5. Let reagents warm to room temperature for 5 minutes prior to use.
6. Place reagents in the reagent rack.

C. HEPTEM Reagent
1. Withdraw a bottle of HEPTEM LYO and a bottle of HEPTEM DIL from package. Open both bottles.
2. Aspirate 200 uL of HEPTEM DIL using an MLA pipette.
3. Dispense 200 uL of HEPTEM DIL into the bottle of HEPTEM LYO
4. Gently swirl the dissolved HEPTEM LYO. Let it rest for 10 min at room temperature.
5. Write date of preparation and expiration on bottle.
6. Place reagent in the reagent rack.

D. Reagent Stability

Table 1: ROTEM Reagent Stability

| Reagent and QC Material | Preparation | Stability after opening |
|---|---|---|
| ROTOL N (NORMAL) | Warm to Room Temp - 5 mins. Pour over diluent and let stand 15 mins. Warm for 5 mins. | 8 hrs. once reconstituted |
| ROTOL P (ABNORMAL) | Warm to room Temp - 5 mins. Pour over diluent and let stand 30 mins. Warm for 5 mins. | 4 hrs. once reconstituted |
| | | |
| STARTEM | Ready for use, for 20 tests. Recalcification reagent. | 8 days |
| INTEM | Ready for use, for 10 tests. Intrinsic activator | 8 days |
| EXTEM | Ready for use, for 10 tests.<br>Extrinsic activator | 8 days |
| APTEM | Ready for use, for 5 tests.<br>Inhibition of fibrinolysis<br>Activated with Extem | 14 days |
| FIBTEM | Ready of use, for 5 tests<br>Platelet inhibitor<br>Activated with Extem | 14 days |
| HEPTEM | Lyophilized reagent<br>Heparin inhibitor<br>Activated with Intem | |
| | Reconstitute with 200 uL of heptem diluent. After opening heptem DIL, store at 2-8°C and is stable until the expiration date on label. Reconstitute 10 min before use. | |
| | Any turbidity in reagent should be considered microbial contamination and reagent should be discarded. | 30 days |

E. Equipment
1. ROTEM delta
2. Touchscreen monitor, and printer

3. ROTEM delta automatic pipette

| BUTTON | FUNCTION |
|---|---|
| SELECT | None |
| ENTER | None |
| < \| > | None |
| ↓ | Tip Eject |
| RESET | Small reset button on the back side of pipette |
| CONFIRM | This central blue button confirms the next pipetting step |

Table 2: Functions of ROTEM Automatic Pipette

4. Note the following during pipette handling:
   a. Hold the pipette vertically during the aspiration of reagents.
   b. Immerse the tip only a few millimeters into the liquids.
   c. To ensure that no air is absorbed during pipetting of blood, immerse tip approximately 10 millimeters.
   d. Only briefly press the start (confirm) button.
   e. Use the integrated pipette holder to put down the filled pipette in order to avoid contamination of the mechanical part of the pipette.

F. Supplies
1. Pipette tips and filters
2. Cups and Pins
3. Measuring cells
4. MC rod
5. Barcode reader
6. Reagent rack
7. Accessories box

**7. Quality Control**

A. See Corewell Health East - ROTEM delta Maintenance and Quality Control - Trenton

**8. Procedure**

A. Log in to the system
1. Touch the screen if the screen saver is active.
2. Select user.
3. Enter password

B. Sample Preparation
1. Check sample for clot (visually or with applicator stick). If the specimen is clotted, a new specimen must be collected.
2. Preheat the whole blood sample for a minimum of 5 to 10 minutes (but no more than 30 minutes) before measurement in the sample preheating station of the ROTEM.

C. Reagent Preparation
1. Take reagent rack in use out of the refrigerator.
2. Withdraw additional reagents for the workday if needed.
3. Write date of opening and expiration on any new bottle.
4. Place reagent rack in its position in the front of the instrument.
5. Wait approximately 5 minutes until the reagents reach room temperature.
6. Select MEASUREMENT icon on touchscreen.
7. Check the lots of all reagents to be used with the ones listed on the screen.
8. Select “All Lots have been Checked” on touchscreen after all lots have been checked.

D. Preparation of the Measuring Cell (MC)
1. Take the cup with the pin in from the storage box.
2. Push the pin in the cup onto the axis chosen for the measurement. Hold the exterior of the cup and push the pin all the way up carefully avoiding touching the pin itself. NOTE: You may

place the cup and pin into the cup holder to load the pin, DO NOT use the MC rod to push down the cup until the pin has been placed.
3. Place the cup with its opening face upwards into the preheated holder.
4. Place the cup holder onto the temperature-controlled work area again.
5. Push and fix the cup in the cup holder using the MC rod, making sure you press straight down.

E. Select Test and Channel
1. Each of the four channels can be selected to start a measurement by touching the screen on the corresponding channel. Channels are 1 to 4 going from left to right.
2. For each channel a test is preset:
   a. Channel 1 = EXTEM
   b. Channel 2 = INTEM
   c. Channel 3 = FIBTEM
   d. Channel 4 = APTEM.
      1) NOTE: If there is a test other than the preset selection, touch the test name on the desired channel and then select the new test from the options listed. The test name above the channel is highlighted in the color code of the ROTEM reagent bottle.
3. If the patient is on heparin (per Beaker), the HEPTEM test should be performed.
   a. Perform the HEPTEM in Channel 4 instead of the APTEM.
   b. When the HEPTEM has completed its measurement, then the APTEM can be run on any channel.

F. Enter Patient Data
1. Touch desired channel.
2. Touch the respective entry field (All Blue fields must be resulted). Enter the following:
   a. Patient ID = Contact Serial Number (CSN) or medical record number may be used.
   b. Sample ID = Place the instrument ID from the tube in this field
   c. Patient first and last name in the appropriate fields
   d. Date of Birth = Place the date of birth here using what is on the specimen tube.
   e. Select the sex of the patient
      1) NOTE: Patient data can be copied from one channel to the remaining channels by selecting “Copy to All”.

G. Start Measurements
1. Mix all reagents gently but thoroughly.
2. Tap the top of the reagent bottles to ensure that no reagent remains in the cap.
3. Open the reagent bottles.
4. Mix the blood sample by repeated slow tilting of the sample.
5. Start the pipetting sequence for the selected channel by pressing the START button on the screen. The instructions (including pictogram) for the next step to be performed are displayed on the screen.
6. Follow the menu navigation of the pipetting program and confirm each step by pressing the blue confirm button. If the pipetting sequence requires a pipette tip change, the blue confirm button stays inactive until the pipette tip is ejected using the eject button.
   a. The pipetting steps can be restarted in the event of pipetting failure. Press “Step Back” (<) in order to go to the previous step. The previous pipetting step is shown allowing to follow the pipetting sequence again.
      NOTE: Always hold the pipette tip above the waste container before you select “Step Back”. The pipette will automatically empty the liquids in the pipette tip when performing this step back.
7. After the last step of the pipetting sequence, the reaction starts.
8. Place the cup holder onto the measuring position using the guiding rods.
   NOTE: The cup holder is held in the measuring position with magnets. In case that the cup holder is not positioned within 30 seconds, the measurement is aborted.
9. Repeat steps 5 – 8 for each test to be performed.

10. Press MULTI-TEM to enable all four channels to be displayed for remote viewing by the physician in the OR. Some of the coagulation parameters are shown as “preliminary values” in the display while a clot is developing. These values are based on a limited amount of data and are replaced by the final values as soon as the appropriate amount of data points are available. Preliminary results are marked with an asterisk (*).

NOTE: Ensure that the OR is aware of the sample ID for the test. This information is needed by them in order to view the test in real time using the MULTI-TEM mode.

H. Finish Measurements
   1. Stop measurement
      a. The measurement is stopped automatically when the maximum measurement time of 60 minutes has been reached.
      b. The measurement can be stopped manually by selecting “Stop Channel (X)”
   2. Print measurement results
      a. Select PRINT button. Select number of TEMograms (measurements) per page. Select 4 per page if all tests have been run.
   3. Save and clear measurement
      a. Select SAVE / CLEAR CHANNEL. The measurement is removed from the screen and is saved in the database.
      b. An erroneous measurement may be discarded.
         1) Select DISCARD CHANNEL and enter comment as to why the result was discarded.
         2) Press ACCEPT. The measurement is removed from the screen and is saved in the database but highlighted in grey on the display.
         3) Should the error message cause the test to be unable to be performed. Then a Comm Log should be utilized in Beaker for documentation of reporting this error.

I. Remove Measuring Cells

NOTE: Remove the cup holder only after the measurement has finished.

1. The cup holder is equipped with an integrated blue pin remover. The cup and pin are removed together with cup holder from the measuring position.
2. Hold the cup holder with one hand and with the thumb of the other hand push the blue pin remover up towards the device. The pin is held in the cup.
3. While holding in the pin remover, pull down the cup holder. Cup holder, pin and cup are removed together.
4. Remove the cup and pin by inserting the metal pin at the right edge of the work area into the bottom of the cup holder.
5. Dispose of cup and pin in a biohazard container.

J. Log off the system
   1. Leave measurement module with the QUIT button.
   2. Confirm with YES
   3. Select Logout.

## 9. Results/Interpretation

A. Reference Ranges

1. Table 3: ROTEM Reference Ranges Source: TEM Systems, Inc.

| | CT (s) | CFT (s) | α Angle (°) | A10 (mm) | A20 (mm) | MCF (mm) |
|---|---|---|---|---|---|---|
| **INTEM** | 122 – 208 | 45 – 110 | 70 – 81 | 40 – 60 | 51 – 72 | 51 - 72 |
| **EXTEM** | 43 – 82 | 48 – 127 | 65 – 80 | 40 – 60 | 50 – 70 | 52 - 70 |
| **FIBTEM** | | | | | 7 - 24 | 7- 24 |
| **APTEM** | **Compare to EXTEM** | | | | | |
| **HEPTEM** | **Compare to INTEM** | | | | | |

2. ROTEM delta reference ranges listed above are for adults 21 years and older and have been determined in 3 US clinical centers on reference group samples with no signs of impaired coagulation. These reference ranges were validated and approved for use at Corewell – Trenton and Farmington Hills Hospitals during the ROTEM delta validation.

B. Measurement Range

| Detection Range | CT (seconds) | A20 (mm) |
|---|---|---|
| Lower | 30 | 3 |
| Upper | > 3600 | 80 |

Table 4: Physical Detection Range for the ROTEM delta

1. The ROTEM delta system measures the Clotting Time (CT), Clot Formation Time (CFT), Alpha Angle (alp), Clot Firmness data (MCF), A10, A20 and Clot Lysis Data LI30, LI60, ML.
2. The measuring range for any of the parameters is defined by physical properties:
   a. CT is measured from 35 sec to the max run time of 8 hrs.
   b. CFT is measured from 1 sec to 8hr – CT
   c. Alpha angle is measured from 1° to 89°
   d. Amplitude is measured from 3 mm to 99 mm (100 mm is defined as indefinite firmness); in physiological conditions, clot firmness > 85 mm is hardly achieved.

C. Reportable Range

| Reportable Range | CT (seconds) | A20 (mm) |
|---|---|---|
| Lower | 40 | 3 |
| Upper | 2000 | 75 |

Table 5: ROTEM Reportable Range

## 10. Interfering Substances

A. Interference with the INTEM assay was seen with aprotinin from 50KIU/mL and spiked in whole blood. INTEM CT results can be prolonged above the reference range when aprotinin is used therapeutically (i.e., liver transplant and cardiac surgery).

B. INTEM is prolonged above the normal range starting at app 0.3 U/mL heparin CT is >10 min. HEPTEM is able to neutralize a heparin effect up to 10 U/mL of unfractionated heparin spiked in whole blood. LMWH has only a minor effect on INTEM. At 1 U/mL (slightly above the therapeutic range), it prolongs CT only mildly. LMWH at 1 U/mL has no effect on HEPTEM CT.

## 11. Limitations

A. ROTEM delta tests are not intended for use on patients under 21 years of age.

1. Per the manufacturer, the ROTEM, delta tests are not intended for use on patients under 21 years of age. Our instrument is not validated for use under 21 years of age. However, due to the nature of when the test is performed, it may not be possible to ascertain the age of the

patient (if the patient comes in as an Undoe/trauma patient). In the event when a patient's age is not available at the time of testing and upon review of the medical records it is ascertained that the patient was under the age of 21 at the time of testing, upon review of the chart a note will be made in the IQCP monthly review log and a RL will be placed by the laboratory. After the RL has been placed and a further review of the chart to include a review of any blood products will be conducted if deemed clinically necessary.

2. Disclaimer to add in the event of a patient under the age of 21 is tested.
   a. Per the manufacturer, the Viscoelastography with Fibrinolysis test on the ROTEM delta is not intended for use for patients under the age of 21. The ranges provided are based on a patient population of 21 years of age and up.

B. Patients with hypofibrinogenemia have not been fully evaluated. Patients with dysfibrinogenemia were not tested.

C. Results from the ROTEM delta should not be the sole basis for a patient diagnosis. The ROTEM delta results should be considered along with a clinical assessment of the patient's condition and other coagulation laboratory tests.

**12. Warnings During Measurements**

A. Usually the warning button is hidden. It only appears if a system error occurs. The status line directly under the according channel turns yellow, the warning button flashes red.
   1. Touch the warning button. The channel with the error is displayed in red.
   2. Record the error message for the eventual requests of the technical service provider (e.g. CCD invalid).
   3. Read the descriptions and instructions under the caption.
   4. Press STOP to abort the running measurement.
   5. Execute the previous instructions under the caption.
   6. Repeat the measurement if the channel is not blocked.
   7. Contact the technical service provider if the error occurs again during the next measurement or the channel becomes blocked from use.

**13. Troubleshooting**

A. For errors during pipetting, see Table 5-7 on page 5 – 31 and Table 8-4 on page 8 – 15 in the ROTEM delta Operator's Manual.

B. For incorrect TEMogram errors, see Table 5-8 on page 5 – 31 of ROTEM delta Operator's Manual.

C. For warning screen errors, see Table 5-6 on page 5 – 30 of ROTEM delta Operator's Manual.

D. For Technical Support contact ROTEM delta TES Systems at (866)597-1652, option 2.

E. If they cannot access the Corewell Health Internet have them contact Corewell Health Service Desk at 888-481-2448. If they cannot access ROTEM LIVE have them contact ROTEM delta TEM System at 866-597-1652, option 2.

**14. Procedures Superseded and Replaced:** This procedure supersedes and replaces the following procedures as of the effective date of this procedure:[32953 Corewell Health East - ROTEM delta – Farmington Hills, 34390 Corewell Health East - ROTEM delta – Trenton]

**15. Revisions**

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

**16. References**

A. ROTEM delta Whole Blood Hemostasis using Thromboelastometry, US Operating Manual, Tem Innovation GmbH, Martin-Kollar-Strasse 13-15 D-81829 Munich/Germany, 2010.

B. ROTEM Training Manual, Tem Systems, Inc., ROTEM, 4309 Emperor Blvd. Suite 100 Durham, NC 27703, 2011.

C. ROTEM Short User Manual, Regulated and Single Use Reagents.

## 17. Procedure Development and Approval

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## 18. Keywords

Not Set