ROTEM DELTA
THROMBOELASTOMETRY

* READ POLICY PRIOR TO STARTING TUTORIAL
QUALIFIED PERSONNEL

- Qualified and Licensed Anesthesia Providers (Faculty and CRNAs).

- Testing personnel are required to take the Initial Orientation and Training, 6 Methods of Competency Exam, and a second Competency Exam within the first year of certification for this POCT.

- Competency exams are then required annually thereafter.
OPERATOR BARCODES

- Upon completion of the Initial Orientation and Training, 6 Methods of Competency, and Written Exam, staff will be issued a barcode ID to be able to use the Rotem delta.

- This barcode in embedded with unique identifiers specific to each staff member.

- **NEVER** share your Barcode ID!
BEFORE TESTING A PATIENT

- Orient yourself to your working area:
  - Locate the Rotem delta instrument
  - Locate Color Printer
  - Locate Testing Supplies:
    - Reagents and Quality Controls
    - Cups & Pins
    - Cup Holder
    - Electronic Pipette
    - Pipette Filter
    - Pipette Tips
    - Pipette holder with integrated waste container
BEFORE TESTING A PATIENT

- Barcode reader
- Adapter (<14mm) Sample Preheater
- MC Rod
- MC Rod Holder
- Reagent Rack delta
What is ROTEM delta Thromboelastometry?

- Using the ROTEM DELTA Instrument is considered **Moderate** in complexity by the FDA.

- ROTEM® is derived from “rotational thromboelastometry”, a powerful technique for the assessment of blood coagulation disorders.

- **Principle:**
  - Blood is added into a disposable cuvette (measuring cell) in a heated cuvette holder.
  - Disposable pin (sensor) is fixed on the tip of a rotating shaft (axis).
  - The rotating shaft is stabilized by a high precision ball bearing system.
What is ROTEM delta Thromboelastometry?

- **Principle** (continued)
  - The rotating shaft is stabilized by a high precision ball bearing system.
  - Shaft rotates back and forth 4.75 degrees.
  - Shaft is connected to a spring to measure elasticity.
  - Exact position of the shaft is detected by reflection of light on small mirror on the shaft.
  - Data obtained from the reflected light is then computer processed into a graphical output.
Principle of Rotem delta Thromboelastometry
ROTEM delta TESTS

- **INTEM (Contact activation)**
  - Monitors the coagulation process via the Intrinsic Pathway.

- **HEPTEM (Contact activation + Heparinase)**
  - Is used to inactivate heparin in patients receiving unfractionated heparin.

- **EXTEM (Thromboplastin)**
  - Monitors the coagulation process via the Extrinsic Pathway.

- **FIBTEM (Cytochalasin D)**
  - Monitors clot firmness after blocking the contribution of platelets.
  - It is always used in conjunction with EXTEM.

- **APTEM (Aprotinin)**
  - Monitors clot firmness after blocking hyperfibrinolysis by aprotinin.
  - It is always used in conjunction with EXTEM.

- **NATEM (Recalcification only)**
  - Monitors the coagulation process after contact-activation by the surface of the measurement cell.
  - This test is use for CAP Survey/Proficiency Testing only, not intended for use on patients.
ROUTINELY MEASURED PARAMETERS

- **Clotting Time, CT (sec)**
  - Speed of fibrin formation; influenced by clotting factors and anti-coagulants.
  - Time to reach 20 mm amplitude from beginning of test.

- **Clot Formation Time, CFT (sec)**
  - Kinetics of clot formation; influenced by platelet level/function and fibrinogen level/ability to polymerize.
  - Time to reach 20 mm amplitude from the time of 2mm amplitude.

- **Alpha Angle, (degree °)**
  - Angle between the middle axis and the tangent to the clotting curve through the 2mm amplitude point.

- **Maximum Clot Firmness, MCF (mm)**
  - Measure for the firmness of clot, i.e., clot quality; influenced by platelets, fibrinogen (concentration and ability to polymerize), Factor XIII, fibrinolysis.

- **A10 (mm)**
  - Amplitude achieved 10 minutes after CT; represents clot firmness.
 ROUTINELY MEASURED PARAMETERS

- **A20 (mm)**
  - Amplitude achieved 20 minutes after CT; represents clot firmness.

- **Lysis Index at 30 min (LI30) and related parameter (%)**
  - Represents fibrinolysis 30 minutes after CT.
  - It is the relation of the amplitude to the maximum clot firmness (% remaining clot firmness).
  - The LI60 parameter describes the remaining clot firmness 60 min after CT.

- **Maximum Lysis, ML (% of MCF)**
  - Abnormal ML at 30 minutes likely indicates fibrinolysis.
  - Percent of clot firmness lost during measurement.

- **Lysis Onset Time, LOT (sec)**
  - Time span from CT to the start of significant lysis in seconds.
  - Significant lysis is defined as 15% amplitude decrease compared to MCF.
*ROTEM® provides the most complete and rapid information on hemostasis.
Universal Precautions should be observed through all phases of the testing procedure.

Samples should be fresh whole blood, collected in a tube containing 3.2% Sodium Citrate (Blue Top Tube).

Samples should be close to 37°C when tested.

Samples must be labeled with Patient’s Identification (2 patient identifiers needed).

Stability: Ambient: generally 4 hours. Refrigerated or frozen samples are not acceptable.

- NOTE: May be shorter (30 minutes) for non-activated thromboelastometry, hyperfibrinolytic samples and samples from patients on heparin therapy.
REAGENTS

☐ Storage and Stability:
  - All opened and unopened reagents are stored at 2-8°C.
  - Opened vials must be used within the stability period after opening. Write the Expiration Date on the vial once it is opened.
  - All reagents must equilibrate to Room Temperature before use for Testing or Reconstitution.
  - During the workday, reagents may be kept at room temperature but vials must be closed tightly immediately after each use.
  - Any turbidity in the reagent should be discarded.
## STABILITY OF THE REAGENTS AFTER OPENING

<table>
<thead>
<tr>
<th>THE REAGENTS</th>
<th>STABILITY AT 2-8°C (after opening)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STAR-TEM 10</strong></td>
<td>8 days</td>
</tr>
<tr>
<td>Recalcification Reagent</td>
<td></td>
</tr>
<tr>
<td><strong>INTEM</strong></td>
<td>8 days</td>
</tr>
<tr>
<td>Intrinsic Activator</td>
<td></td>
</tr>
<tr>
<td><strong>EXTEM</strong></td>
<td>8 days</td>
</tr>
<tr>
<td>Extrinsic Activator</td>
<td></td>
</tr>
<tr>
<td><strong>APTEM</strong></td>
<td>14 days</td>
</tr>
<tr>
<td>Inhibition of Fibrinolysis</td>
<td></td>
</tr>
<tr>
<td>Activated with Extem</td>
<td></td>
</tr>
<tr>
<td><strong>FIBTEM</strong></td>
<td>14 days</td>
</tr>
<tr>
<td>Platelet Inhibitor</td>
<td></td>
</tr>
<tr>
<td>Activated with Extem</td>
<td></td>
</tr>
<tr>
<td><strong>HEPTEM</strong></td>
<td>30 days</td>
</tr>
<tr>
<td>Lyophilized Reagent</td>
<td></td>
</tr>
<tr>
<td>Heparin Inhibitor</td>
<td></td>
</tr>
<tr>
<td>Activated with Intem</td>
<td></td>
</tr>
<tr>
<td>Reconstitute with 200 ul of heptem diluent</td>
<td></td>
</tr>
<tr>
<td>Reconstitute 10 minutes before use</td>
<td></td>
</tr>
</tbody>
</table>

- **HEPTEM** Reagent is reconstituted using the Liquitrans Menu of ROTEM.
  - Enter 200 ul as volume to be aspirated.
  - Press START
  - Follow the instructions on the Screen.
ROTEM REAGENTS

STARTEM

INTEM

EXTEM

APTEM

FIBTEM

HEPTEM
Internal / Equivalent Quality Control (EQC)

- Continuous self-monitoring system that monitors the performance of the axis movement, sensors and temperatures.
- Operator access the Service Menu and evaluates the following values per channel:

<table>
<thead>
<tr>
<th>Value</th>
<th>Definition</th>
<th>Target Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitude</td>
<td>Measurement confirming the movement of the axis and proper functioning of the supporting ball bearings.</td>
<td>4400 to 4850</td>
</tr>
<tr>
<td>Center</td>
<td>Measurement indicating the location of the amplitude on the CCD chip.</td>
<td>-832 to 708</td>
</tr>
<tr>
<td>Variance</td>
<td>Measurement providing information about the mechanical status of each channel.</td>
<td>&lt;12,000</td>
</tr>
<tr>
<td>Temperature</td>
<td>Measurement of the instrument temperature settings as well as the pre-warming station.</td>
<td>35°C to 38.5°C</td>
</tr>
</tbody>
</table>
QUALITY CONTROL

- Internal Quality Control is evaluated for accuracy daily on each day of use of the instrument.

- **All USERS must run Daily Internal Quality Control** as part of the 6 Methods of Competency.

- A print out is **REVIEWED, SIGNED and FILED** by the operator who evaluated the data.
Anytime a Service Value is Out-Of-Range the following procedure is to be followed.

- Re-evaluate the service value that is Out-Of-Range.

- If any value remains Out-Of-Range, and cannot be quickly remedied, then determine if the values are affecting all channels or if the value is impacting a particular channel.

- Only use channels that have passed the Service Value check for patient testing.

- Document all corrective actions when Internal Quality Control is Out-Of-Range.

- If it can be determined that a single channel is involved, contact Point of Care Services.
Sample Printout of Daily Internal Quality Control

![Screen shot of a ROTEM® Service module showing quality control parameters including gain, temperature offset, phase shift, amplitude, and variance for different channels.](image)
External / Liquid Quality Control (LQC)

- Storage and Stability:
  - All opened and unopened reagents are stored at 2-8°C.
  - Controls must equilibrate to Room Temperature before Reconstitution.

### CONTROLS

<table>
<thead>
<tr>
<th></th>
<th>Stability after Reconstitution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotrol N Level I Control</td>
<td>8 hours</td>
</tr>
<tr>
<td>Rotrol N Dissolves with Rotrol N Diluent</td>
<td></td>
</tr>
<tr>
<td>Rotrol P Level II Control</td>
<td>4 hours</td>
</tr>
<tr>
<td>Rotrol P Dissolves with Rotrol P Diluent</td>
<td></td>
</tr>
</tbody>
</table>

Rotrol N

Rotrol P
QUALITY CONTROL

Rotrol N (Normal Control) and Rotrol P (Abnormal Control)

- Required External QC materials for the ROTEM System.
- These control tests are run to identify potential problems with:
  - Reagents, Consumables, User Technique
- External QC must produce acceptable results that fall within the ranges for any reportable parameter.
- QC is lot-specific. Refer to the package insert of the QC Material in use for valid Reference Ranges.
QUALITY CONTROL

- Both Rotrol N and P controls are run at least once per week of use of the instrument and any of the following occasions before:
  - After preventive maintenance is performed
  - Whenever a new shipment or a new lot number of reagent and quality control is received.
  - Whenever a value from the Service Menu is Out-Of-Range and cannot be corrected.

- Run External Quality Control **every Wednesday**.

- **All USERS must run Weekly External Quality Control** as part of the 6 Methods of Competency.
QUALITY CONTROL

Rotrol N and Rotrol P Preparation:

- Reconstitute Rotrol N and Rotrol P with its particular diluent.
  - Rotrol N Lyo + Rotrol N Dil
  - Rotrol P Lyo + Rotrol P Dil

- Close the vial with a rubber stopper and screw up.
- Gently invert and swirl the lyophilisate to dissolve.
- Allow the reconstituted control to sit at Room Temp.
  - Rotrol N and Rotrol P – 30 minutes

- Invert each control.
- Check measurement temperature in the status line (37°C / 98.6°C).
- **Pre-warm for 5 minutes at 37°C** on the temperature controlled work area.
- Mix once again prior to testing the controls.
QUALITY CONTROL

Actions when External Quality Control Out-Of-Range

- If one or more values Out-Of-Range in one or more channels – Repeat QC for channel with **SAME** QC vial (one vial good for 4 tests).

- If still one or more values Out-Of-Range in one or more channels – Repeat QC for channel with **NEW** QC vial of the appropriate test.

- If one or more values Out-Of-Range after the repeat – Repeat QC for channel with **NEW** QC vial from a **New Box** of the appropriate test.

- Out-Of-Range: Do not use affected Channel(s). All other channels are okay to use. Inform Super User.

- **Document all remedial action taken.**
ROTEM
Weekly QC Testing Algorithm

Perform QC test

One or more values out-of-range in one or more channels

Repeat QC for channel with same QC test vial (one vial good for 4 tests)

If still one or more values out-of-range in one or more channels

Repeat QC for channel with new QC vial of the appropriate test (e.g. QCinP)

One or more values out-of-range in one or more channels

Repeat QC for channel with new QC vial from a new box of the appropriate test (e.g. QCinP)

Out of range: Do not use affected channel(s).
(All other channels are ok to use)
Inform Super User

Weekly QC passed! Document QC test with
1. Screenshot
2. Printout
3. Sign off
Perform External Quality Control

- QC must be performed regularly by every ROTEM user.
- The control is performed on all channels (2 channels INTEM and 2 channels EXTEM).
- Choose the corresponding QC-Test:
  - Rotrol N – QCinN (Intem) & QCexN (Extem)
  - Rotrol P – QCinP (Intem) & QCexP (Extem)
- Select the correct Rotrol N or P lot number
- Follow the pipetting sequence

**NOTE:** The only difference between the pipetting sequence for the routine tests and the ones for the control tests, is that instead of blood samples, controls are pipetted.
Measurement Preparation

- Prepare tests according to test specific instructions
- Obtain and process samples according to the instructions.

- **Usage of the Pipette:**
  - Hold the pipette vertically during aspiration of reagents.
  - Immerse the tip only a few millimeters into the liquids.
  - To ensure that no air is absorbed during pipetting of blood, immerse tip approximately 10 millimeters.
  - Only press briefly the start button.
  - Use the integrated pipette holder to put down the filled pipette in order to avoid contamination of the mechanical part of the pipette.
Patient / QC Testing

- **Log in to the system**
  - Touch the screen if the screen saver is active.
  - Select User (Last Name).
  - **Note:** *If user training will (has) expire(d), confirm pop up and act accordingly in order to avoid future operator lock out.*
  - Enter Password (License Number).

- **Check the lots of the reagents to be used with the ones on the screen.**
  - Change any reagent lots if required
  - Confirm with *I have checked all reagent lots in use.*
Patient / QC Testing

- The color of the status line indicates the status of the measurement for each channel.
  - 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.
Patient / QC Testing

- Reagent Preparation
  - Take reagent rack with reagents already in use of the refrigerator.
  - Withdraw additional fresh reagents for the work day from the packages in the refrigerator.
  - Write the expiration date into given field on any new bottle.
  - Refill reagent rack.
  - Place the reagent rack to its position in the front of the instrument.
  - Wait approximately 5 minute until the reagent reaches room temperature.
Patient / QC Testing

- Preparation of the Measuring Cell
  - Take the cup with the pin in it from the storage box.

- Sample Preparation
  - Measure the blood sample directly after sampling.
  - Preheat the blood sample for 5-10 minute before measurement in the sample preheating station of the ROTEM delta

- Select Channel
  - The active selected channel is highlighted in blue.
  - Each of the four channels can be selected to start a measurement by touching the screen on the corresponding channel.
  - To obtain or view of the 4 channels press multi-TEM.
Patient / QC Testing

- **Enter Patient Data** Touch one of the four channels
  - Touch the respective entry field
  - Enter patient data: Medical Record Number Only.
  - Patient data can be copied from one channel to another by **Copy, Paste or Copy to all**.

- **NOTE:** The names of mandatory fields are displayed in blue. A message prompting to fill them out will appear if pipetting is started before all mandatory fields are filled out.
Patient / QC Testing

Select Test
- For each channel a test is preset in the menu Setup.
- Touch the test name on top of the selected channel.
- A list with all possible tests pop up.
- Select required test by touching it.
- The new test name above the channel is highlighted in the color code of the ROTEM reagent bottle.
Start Measurement

- Mix reagent gently and thoroughly.
- Open the reagent bottle.
- Mix the blood sample / liquid QC by repeated slow tilting of the sample.
- Start the pipetting sequence for the selected channel by using the **Start** button.
- Follow the menu navigation of the pipetting program and confirm each step by pressing the blue start button of the pipette.
- Place the cup holder onto the measuring position using the guiding rods.
- Press <Enter> to confirm that cup holder is in place.
Stop Measurement

- Measurement is stopped automatically when the maximum measurement time determined in the module SETUP is reached.
- Stop measurement manually by selecting Stop channel x

Print Measurement Results

- Channel is not yet cleared/discarded.
- Select Print button.
- Select number of TEMograms (measurements) per page.
  - 1 TEM (1 TEMogram over 60 min and additionally the same TEMogram over 8 hours)
  - 4 TEM (4 different TEMograms of 60 min each)
Patient / QC Testing

- **Clear Channel**
  - Select **Clear channel**
    - The measurement is removed from the screen.
    - The measurement is saved in the database.

- **Remove Measuring cells**
  - Remove cup holder only after the measurement has finished.
  - Hold the cup holder with one hand and push, with the thumb of the other hand, the blue pin remover up towards the device.
  - While holding in the pin remover, pull down the cup holder.
    - Cup holder, pin and cup are removed together.
Patient / QC Testing

- Remove cup and pin
  - Insert metal pin at the right edge of the work area into the bottom of the cup holder.
  - Push the cup holder down the metal pin.
  - Dispose of cup and pin according to the effective regulations for bio hazardous materials.

- Log off the system
  - Leave measurement module with the Quit button
  - Confirm with Yes.
  - Select Logout
    - The log in screen is shown.
Reporting / Documentation Results

- **Place printed copy of results in the Patient’s Medical Chart.**

- Printed Reports must have sticker / label with Patient’s Identification (at least 2 independent identifiers).
The maintenance schedule consists of daily, weekly, quarterly and yearly timetables.

Daily Maintenance

- Clean and disinfect cup holder.
- Clean and disinfect the lower surface of the measuring block (around the axis).
- Check the pipette filter for blood stains and replace if required.
Limitations of Method

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

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 diagnosis. The Rotem® $delta$ results should be considered along with a clinical assessment of the patient’s condition and other coagulation laboratory tests.

D. All controls are subject to the limitations of the test system. Variables such as temperature, reagent, specimen stability, instrument properties and individual techniques may affect the final result. **ALWAYS STRICTLY** follows the Manufacturer’s Guidelines for the device and reagents.

E. Carryover Studies determine whether high concentration samples run immediately before low concentration samples cause falsely elevated results. Carryover studies are not required for the Rotem® $delta$ due to its independent channel test design.
F. Interferences:

1. Rotem® delta results are affected by the antifibrinolytic drugs aprotinin, tranexamic acid (TXA) and epsilon aminocaproic acid (EACA).

2. In-Tem® based assays: In-Tem® CT results can be prolonged above the reference range when aprotinin is used therapeutically (e.g., liver transplant and cardiac surgery). No interference was found with tranexamic acid up to 60 µg/ml (2x clinical dose) and with EACA up to 600 µg/ml (2x clinical dose) spike in whole blood.

3. Ex-Tem® based assays: Ex-Tem® was found insensitive to interference with any of the antifibrinolytic drugs. When using Ex-Tem® as an activator the parameters are unaffected up to a heparin concentration of 4 U/ml UFH in whole blood.

4. Unfractionated heparin: Hep-Tem® is able to neutralize a heparin effect up to 10 U/ml unfractionated heparin spiked in whole blood.

5. Na-Tem® test is highly sensitive to heparin. A use of the test in heparinized samples is not recommended.

MSDS – Located on the SFGH-POCT.org website under “ACT”
For Further Questions or Information
Contact POCT Services

SFGH-POCT.org