PROCEDURE
Corewell Health East - ROTEM delta Maintenance and Quality Control - 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 #: 34391

Version #: 2

Effective Date: 10/17/2025

Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Hematology

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1. **Principle**
   Maintenance and Quality Control (QC) must be performed in order to guarantee correct operation of the ROTEM delta system. The ROTEM system requires only minor maintenance if utilized according to the regulations of cleaning the surfaces, cleaning of the cup holder, replacing the pipette filter, cleaning of the pipette if necessary, and cleaning or replacing the pin remover. Quality Control is done to ensure proper functionality.

2. **Responsibility**
   Personnel who have completed the competency requirements will perform these tasks.

3. **Reagent/Equipment Needed**
   A. Kim-wipes (lint-free wipes)
   B. Distilled water
   C. Sani-Cloth Germicidal Wipes (55% Isopropyl alcohol and 45% ammonium chloride) or 70% Isopropyl alcohol prep pads
   D. Cotton swabs
   E. Clean Ring Rod
   F. Measuring Cell (MC) Rod
   G. Pipette filter
   H. Filter tweezers
   I. Pin remover

4. **Daily Maintenance**
   A. Switch off the instrument by pressing the blue power button on the right side of the instrument.
   B. Clean and disinfect the outer surface with either a Sani-Cloth wipe or Isopropyl alcohol pad.
   C. Clean and disinfect the cup holder with either a Sani-Cloth wipe or alcohol pad.
   D. Clean the pipette with a damp Kim-wipe by wiping the outside of the pipette.
   E. Visually inspect the pipette filter and replace if contaminated with blood. (See section on changing pipette filter under weekly maintenance).

F. Check and print Internal QC values and Temperature.
   1. Switch on the ROTEM delta by pressing the blue power button. Wait until the instrument reached operating temperature (approx. 5 minutes).
   2. Log into ROTEM software.
   3. Open the Service menu and select the settings tab.
   4. Read the temperature values of the 4 testing channels. The temperature readings should be between 35.5° and 38.5° Celsius (C).
   5. Wait for the curvature graphs to appear and the values to stabilize (approx. 3 to 5 minutes).
   6. Read the values of the Amplitude, Center and Variance. The values should fall within the following ranges:
      a. Amplitude: 4400 to 5100
      b. Center: -832 to +708
      c. Variance: <12000
   7. Once values are within range, press the Print Screenshot button and file the printout under the Daily QC section of the ROTEM QC logbook.
   8. Document performance of daily maintenance on the Maintenance Log Sheet.
   9. Corrective Action for Internal QC out of range:
      a. Re-evaluate the service value that is out of range (i.e. if the temperature is out of range); reassessing to determine if the value falls within range is the first acceptable corrective action.
      b. If any value, variance, center, amplitude, or temperature is out of range and cannot be quickly remedied (i.e. by cleaning the measurement position), then determine if the values are affecting all channels or if the value is impacting a particular channel.
      c. If it can be determined that a single channel is involved, call ROTEM technical support or clean the Clean Ring.
      d. Document all corrective actions on the printed screenshot and IQCP Problem Documentation Log for Farmington Hills. For the Trenton campus document corrective actions on the QC sheet.
      e. Only use channels that have passed the Internal QC Service Value check for patient testing.
      f. In the event that one or more channels is out of service, triage patient testing as follows:
         1) INTEM
         2) EXTEM
         3) FIBTEM
         4) APTEM
      g. Run external QC if needed per service or management.
   10. Ambient Room Temperature Check (FH).
      a. Document ambient room temperature in Hematology on the Daily Temperature Readings Log sheet.
      b. Acceptable range of ambient room temperature is 15 – 30°C (59 – 86°F).

5. Weekly Maintenance and Quality Control (QC)

A. Check and Replace pipette filter.
   1. Farmington Hills campus, replace the filter as necessary.
   2. Trenton campus, replace the filter at least bi-weekly.

B. To remove the filter:
   1. Remove filter with supplied filter tweezers.
   2. Insert new filter with filter tweezers.
   3. Document on ROTEM Maintenance Log.

C. Perform Database backup.

D. External controls are performed weekly in accordance with the ROTEM Individualized Quality Control Plan (IQCP).
   1. Reconstitute the control material by transferring the contents of the diluent vial into the lyophilisate vial.

a. NOTE: The diluent vial should not be emptied completely with a pipette. The vial should be poured over a drop left in the diluent vial.
2. Tightly close the vial with the rubber stopper and screw cap shut.
3. Gently invert and swirl the lyophilisate to dissolve.
   a. NOTE: Ensure that the lyophilisate dissolves completely.
4. Allow the plasma to reconstitute in the closed vial for the following times.
   a. ROTROL N to reconstitute for at least 15 minutes.
   b. ROTROL P to reconstitute for 30 minutes.
5. After the required time carefully mix the control material by gentle swirling.
6. Place the control material on the warming plate on the instrument for 5 minutes.
7. After the warming period, mix the control material again by carefully inverting and swirling the vial. After this the control is ready for use.
8. Log in to the System.
9. From the main menu, select the MEASUREMENT icon.
10. Select QC test from the pull-down menu (QCinN, QCinP, QCexN, QCexP).
11. Place pins on each axis.
12. Prepare measuring cells with cups and fix with MC rod. Gently mix controls by swirling (do not shake). NEVER INVERT!
13. Press START.
14. Follow the onscreen pipetting sequence.
    a. NOTE: The only difference between the pipetting sequences for the routine tests and the ones for the control tests is that instead of blood samples, controls are pipetted.
15. Let the QC measurement run until parameter A20 has been reached and the runtime equals 30 – 35 minutes.
16. Check and confirm that the CT, Alpha (α) angle, A10, and A20 have passed.
    a. NOTE: QC ranges are lot specific and are automatically saved in the system after scanning the ROTROL box upon the arrival of a new lot. QC ranges are also listed on the package insert.
    b. Select ‘Print’ and press ‘4’ so all TEMS will print on one page and initial, date and file under Weekly QC in ROTEM QC & Maintenance logbook.
    c. Initial and date performance of Weekly QC on the ROTEM Maintenance / QC sheet.
17. Corrective Action for External QC out of range.
    a. Repeat measurement on that channel or a second channel.
       1) If repeating on the same channel and the results are acceptable then the instrument is cleared for patient testing.
       2) If repeating QC on a second channel, perform one of the other QCs on the original channel. If the results are acceptable, proceed with patient testing. (This is to ensure that all channels have been QC’d and working as anticipated).
    b. If the repeated QC is out, repeat with fresh reagents.
    c. If the QC is out with fresh reagents, repeat with fresh control material.
    d. If QC remains out, contact ROTEM technical support. Patient samples cannot be run until QC issue is resolved.
       1) At the Trenton campus, the Trauma team must be notified that the ROTEM testing will not be available until the issue is resolved.
    e. Record all corrective actions on the IQCP Problem Documentation Log for Farmington Hills and document on the QC printout.
18. To stop the QC tests, highlight the channel and select stop on each of the 4 channels.
19. Select “Save/Clear”.
20. Discard used cups and pins.

E. Quality Control of new lots.
   1. External QC is performed whenever a new shipment or lot number of reagent is received and prior to use on the ROTEM.

2. For ROTROL N and ROTROL P the new lot of controls will be tested with the current lot of INTEM and EXTEM reagents using the new lot specific ROTROL ranges provided by the manufacturer.
    a. Perform QCexN, QCinN, QCexP, and QCinP with the new lot of ROTROL N and ROTROL P.
    b. Record results on New Lot QC worksheet and indicate if QC results are acceptable, initial, date, and file in ROTEM Reagent Inventory and New Lot QC logbook (for the Farmington Hills campus) or the ROTEM Maintenance logbook (Trenton campus).
3. For INTEM and EXTEM the new lot of reagents will be tested with the current lot of ROTROL N and ROTROL P using the lot specific ranges provided by the manufacturer.
    a. Perform QCexN, QCexP for new lot of EXTEM and QCinN, QCinP for new lot of INTEM.
    b. Record results on the New Lot QC worksheet and indicate if QC results are acceptable, initial, date and file in the ROTEM Reagent Inventory and New Lot QC logbook (for the Farmington Hills campus) or the ROTEM Maintenance logbook (Trenton campus).
4. New lots of Fib-Tem reagent.
    a. New lots of the Fib-Tem reagent will be tested with the current lot of ROTROL N and ROTROL P QC material using the lot specific ranges for the EXTEM reagent provided by the manufacturer. This will test the EXTEM activator in the Fib-Tem reagent. To verify the integrity of the Cytochalasin D component of the Fib-Tem reagent, a normal donor control can be used. The normal donor control must be free from any medication known to affect platelet function for a minimum of 7 to 9 days.
    b. Performing the quality control at the Farmington Hills campus.
        1) Perform the QCexN and QCexP for the EXTEM reagent if it has not been performed recently.
        2) Perform a platelet count and Fibrinogen Assay on the normal donor control to verify the appropriateness of the donor.
        3) Perform the EXTEM and Fib-Tem test on the normal donor control.
        4) Record the results on the Fib-tem New Lot worksheet and indicate if the QC results are acceptable, initial, date and file in the ROTEM Reagent Inventory and New QC logbook.
    c. Performing the quality control at the Trenton Campus.
        1) Perform the QCexN and QCexP for the EXTEM reagent in conjunction with running the Fib-Tem reagent for both levels of QC.
        2) This will give a direct comparison and ranged on the same sheet of paper.
        3) Document the acceptability of the Fib-Tem QC results are acceptable, date and initial the printout, and file in the ROTEM Maintenance and QC logbook.
5. New lots of APTEM reagent.
    a. For new APTEM reagent lots will be tested with the current lot of ROTROL N and ROTROL P using the lot specific ranges for the EXTEM reagent provided by the manufacturer. This will test the activator EXTEM. A separate control of the antifibrinolytic component is not required. The APTEM assay should always be performed in conjunction with an EXTEM assay and is used as confirmation test for hyperfibrinolysis. Therefore, the control for APTEM is integrated in the assay.

6. Semi-annual Maintenance

A. Semi-Annual Maintenance; replace the integrated pin remover on the cup holders.
    1. Push the flat part of the MC Rod into the opening at the underside of the cup holder lifting and pushing the sealing tongue forward.

NOTE: Do not press or scratch the sealing tongue or use brute force to directly on the pin remover.

2. Install the new pin remover.
   a. Insert the sealing tongue deep into the central opening of the cup holder as pictured.

   b. Press the springs to the left and right at the pin remover carefully into their guides.

   c. Press the pin remover unit it clicks, and the springs slide into their final position.

7. As Needed Maintenance

A. Removal and cleaning of the Clean Ring around the channel axis (to be performed if daily channel values are not within specifications).
   1. Power off system by pressing blue on/off button on right side.
   2. Place Clean Ring Rod around the axis.

3. Fit the two little pins of the Clean Ring Rod into the 2 little holes of the Clean Ring from the concerned channel.

4. Turn the Rod, unscrew and remove the Clean Ring.
5. Let the Clean ring soak in soapy water.
6. Clean off any remaining dirt with a moist, cotton swab.
7. Rinse with distilled water
8. Let the Clean Ring dry.
9. Clean the Clean Ring's position around the axis (in the measuring block) with moist cotton swab.
10. Let the Clean Ring's position dry.
11. Replace the Clean Ring into its position around the channel axis with the Clean Ring Rod.
12. Switch the system on.
13. Check the CCD chip values again, as described in daily maintenance.
14. Contact technical service if any values are still out of specification.

B. Maintenance of the ROTEM electronic eLine pipette.
   1. Cleaning and disinfection of individual parts.
      a. Dismantle pipette for cleaning and disinfection completely.
      b. Disconnect ROTEM delta from power outlet.
      c. Remove pipette cable.
      d. Press the locking buttons on both sides.
      e. Remove the cover.
      f. Remove plug.

g. Mount cover again.
h. Unscrew and remove tip ejector.
i. Unscrew tip cone.
j. Remove tip cone, tip holder and spring.
k. Remove pipette filter - piston is exposed.
l. Unscrew and remove piston.

2. Cleaning
   a. Clean individual parts with an appropriate disinfectant or mild chemical cleanser. Clean the interior of the tip ejector and the tip holder with a cotton cleansing tissue.
   b. Rinse thoroughly with distilled water.
   c. Let parts dry.
   d. Grease the piston very thinly with the grease provided.
3. Disinfection
   a. Place the individual parts (except pipette head) for at least 30 minutes into a beaker with appropriate disinfectant.
   b. Rinse thoroughly with distilled water.
   c. Let parts dry.
   d. Grease the piston very thinly with the grease provided.
4. Reassemble pipette
   a. Screw in the piston.
   b. Place the spring on the piston.
   c. Push the tip holder into position.
   d. Screw tip cone back to its position.
   e. Insert a new pipette filter using filter tweezers.
   f. Fix tip ejector.
   g. Open cover from pipette head.
   h. Connect pipette cable.
   i. Close cover.
   j. Connect the pipette cable to the socket on the side of the device.
   k. Start ROTEM system.
   l. Open LIQUITRANS menu.
   m. Check pipette function by pipetting different small and large volumes.
   n. Check the function of the tip ejector.
5. ROTEM eLine pipette calibration
   a. The ROTEM pipette will be sent out for calibration annually or if decontamination has been performed.

8. Revisions

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

9. Procedures Superseded and Replaced: This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [32954 Corewell Health East - ROTEM delta Maintenance and Quality Control – Farmington Hills]

10. References

A. ROTEM delta Whole Blood Hemostasis using Thromboelastometry, US Operating Manual, Tern Innovation GmbH, Martin-Kollar-Strasse 13-15 D-81829 Munich/Germany, 2010.
B. ROTEM delta Training Manual, Tern Systems, Inc., ROTEM, 4309 Emperor Blvd. Suite 100 Durham, NC 27703, 2011.
C. ROTEM Short User Manual, Regular and Single Use Reagents.
D. Fib-Tem Instructions for Use. Version 0014 USA DOC
E. AP-Tem Instructions for Use. Version 0012 USA DOC

11. Procedure Development and Approval

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12. Keywords

Not Set