ROTEM Thromboelastometry
Department of Clinical Laboratories
The Ohio State University Wexner Medical Center

Laboratory:	Document Type:	Original Date Adopted:	Previous Document:
Point of Care Testing	Procedure	02/21/2013	POC- 13 Revision 9

Document Author:	Document Owner:	Acknowledgement / Required Copy Holders*:
Chelsie Ross, MLS(ASCP)cm	Karen Scott	Testing personnel documents acknowledge of reading procedures during training and annual competency

Approval*:
Coagulation Division Director Ohio State University Wexner Medical Center Laboratory Medical Director

Approval and Acknowledgements
Refer to QPulse system and Document Details report for laboratory directors(s)' electronic signature approval, employee acknowledgment and effective date.

1. **PRINCIPLE**
   1.1. The ROTEM *delta* system measures the qualitative and quantitative coagulation status of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions.
   1.2. The ROTEM system records kinetic changes of clot formation, retraction and lysis in a citrated whole blood sample.
   1.3. An oscillating vertical axis is suspended within a disposable cup containing whole blood; this axis rotates 4.75°, and the rotation is detected optically via a mirror plate at the upper end of the axis. If no clotting takes place, the movement is not obstructed. When a clot is formed, it attaches itself between the pin and cup, restricting movement.
   1.4. As a clot forms and lyses, the analyzer displays a graphical representation of the coagulation curve-clot firmness over time, including some numeric parameters describing the curve quantitatively.
   1.5. Quantitation of intrinsic (INTEM), extrinsic (EXTEM), fibrinogen (FIBTEM), aprotinin (APTEM), and the effect of unfractionated heparin on the intrinsic pathway (HEPTEM) measurements are achieved using these test-specific reagents.
   1.6. The coagulation evaluations provided by the ROTEM *delta* are commonly used to assess clinical conditions in organ transplantation, cardiovascular surgery, cardiology procedures and trauma to assess post-operative hemorrhage and/or thrombosis.

2. **SCOPE OF DOCUMENT:**
   2.1. This document applies to the following staff titles that are authorized to order, interpret and assess Rotem parameters (CT, CFT, α Angle, MCF, A20, LI and ML) upon completion of initial training (CBL Rotem 101 Basics of Interpretation and Clinical Application): Cardiothoracic and Vascular Anesthesiologist Hematologists and Heptologists. Qualified personnel only must interpret all ROTEM results.

3. **RESPONSIBILITY:**
   3.1. The coordinators and manager are responsible for maintaining this document and ensuring biennial review. The laboratory division director over coagulation is responsible for approving all changes, and reviewing biennial when there are no revisions. The laboratory medical director is responsible for establishing and approving all changes before activating document

4. **SPECIMEN COLLECTION:**

WARNING: BODY FLUID PRECAUTION
Blood is a body fluid capable of transmitting infectious diseases. Universal precautions for the prevention of the transmission of blood borne pathogens must be in effect at all times.

   4.1. Patient Preparation: All institutional policies and procedures should be followed in the collection of blood samples. Verify patient identification using at least 2 identifiers.
      4.1.1. During a surgical procedure patient is identified per OSU timeout.
   4.2. Specimen type:
      4.2.1. One-1.8 mL of fresh whole blood collected in 3.2% citrated tubes, achieving a 9:1 ratio of blood: citrate.
      4.2.2. Sample is stable at room temperature (23°C) up to four (4) hours after collection for most coagulation-based testing.
      4.2.3. DO NOT store between 2-8°C.
   4.3. Handling Conditions:
      4.3.1. Samples of patients that are not analyzed immediately after sampling have to be pre-warmed 5-10 minutes in the Sample Preheating Station before analyzing.
   4.4. Amount:
      4.4.1. The ROTEM *delta* requires 300 µL per reaction cup. One completely filled 1.8 mL citrated tube is sufficient for testing.
   4.5. Unacceptable specimens:
      4.5.1. Clotted samples

4.5.2. Insufficient quantity (QNS) samples (e.g. blood is less than 1.8 mL)

5. **REAGENTS/SUPPLIES:**

5.1. Hardware

Figure 3-1 shows components of the ROTEM® *delta*, Table 3-2 shows their description.

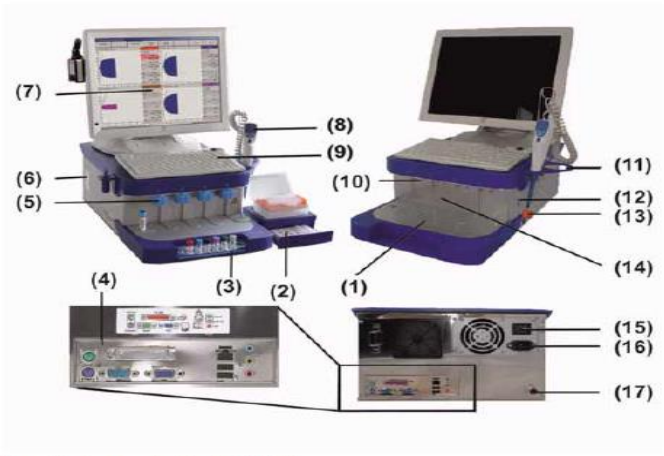


Figure 3-1: Components of the ROTEM® *delta*

5.2.

Component	Description
1. Temperature controlled work area with ejector	The work area serves as a preheating station for cup holders and additionally contains a sample preheating station. The temperature in the work area is maintained at the preset measurement temperature (generally 37˚C). To facilitate removal of the blood-filled measurement cells (cups with pins), a metal pin as measuring cell ejector is integrated into the work area.
2. Accessories box	Cups and pins within their package are stored in the drawer. The box of pipette tips can be placed on top.
3. Reagent rack	Holds the reagents during measurement.
4. Sockets	Sockets on the rear side of the device for power cable and screen cable etc. All standard sockets on the computer device are described on the adhesive labels.
5. Measurement station with cup holders	Every ROTEM system has four independent channels. The channels are tempered to 37˚C +/- 1.0˚C. The cup holders are of massive, stainless material and contain two high power magnets for fixing.
6. Type label	The type label provides information on model, serial number, date of manufacturing, bus bar, CE mark, CSA mark and manufacturer.
7. Touch screen with barcode scanner	The software is controlled by the touch screen. The barcode scanner scans reagents, controls and samples.
8. System pipette	Using the electronic system pipette, semi-automatic and software controlled pipetting and mixing of liquids is possible.
9. Keyboard with integrated waste container and pipette cable guide	The keyboard with the integrated track ball is connected to one of the four USB slots at the rear side of the instrument. The keyboard is placed in front of the touch screen.
10. Axis	The pins are placed on the central, partly slotted axis.
11. Pipette holder with integrated waste container and pipette cable guide	Holds the pipette, the pipette cable guide and a plastic waster container.

12. On/off switch	The blue button on the right side of the device turns the ROTEM on (the button glows blue, software is starting).
13. Pipette socket	Connection of the system pipette.
14. Guiding rods and rails	Guides the cup holder when placing it on the axis and ensures the proper positioning of the cup under the axis.
15. Main switch	The switch connects the ROTEM to or disconnects it from the grid. Switch I – equipment is switch on Switch O – equipment is switched off
16. Power cable	Utilize only the original power cord.
17. 6 pin plug	Reserved for further use.

5.3. Software

Module	Description
Measurement module	In the measurement module, you can select, start, perform and run tests
Database	In the module Database, you can manage the sample measurements and QC results and further evaluate them.
USB Stick	Data in the ROTEM system is usually transferred via a USB stick. The USB stick is used for backup/restore and the export of TEMograms and numerical data.
File system	In the module File System and in the sub modules Admin Tools and User, you can manage some system settings.
Liquitrans	The Liquitrans module guides you step by step through the pipetting of up to 2000 µl liquid with the automatic pipette.
Service	In the module Service, you influence the recording of raw data.
Setup	In the module Setup, you change system settings. Reagent and control tracking features are also available in this module.

5.4. Reagents: Refrigerated reagents are stored in the POC department, the Blood Bank refrigerator in the OR, or the respiratory therapy refrigerator. The refrigerator is monitored by continuous monitoring system. Do not use any reagent beyond the manufacturer's expiration date or the new expiration date, whichever comes first.

5.4.1. Hep-TEM

5.4.1.1. Hep-Tem reagent (heparinase and recalcifier) monitors the intrinsic pathway in the presence of unfractionated heparin. By adding heparinase to a heparinized blood sample, the heparin in the sample is degraded and the anticoagulant activity is removed. This enables blood coagulation to be evaluated without the effect of heparin. The test is usually compared with an In-Tem test. The reagent is used to inactivate heparin in patients receiving unfractionated heparin.

5.4.1.2. Reconstitute Hep-TEM Lyo (Ref# 503-08) with 200 µL Hep-TEM Dil (Ref# 800282) using the Liquitrans pipette.

5.4.1.3. Allow to reconstitute for 10 minutes in the closed container.

5.4.1.4. Before use, mix gently by swirling the bottle.

5.4.1.5. Store 2-8°C up to 30 days after reconstitution.

5.4.2. In-TEM

5.4.2.1. In-Tem reagent (activator) is used to monitor the coagulation process via the intrinsic pathway. In the thromboelastic measurement with ROTEM, the clotting process is started after adding In-Tem and Star-Tem reagent to the sample.

5.4.2.2. In-TEM is ready for use; no reconstitution necessary.

5.4.2.3. Reagent is stored at 2-8°C until expiration date from manufacturer, or within eight days of opening, whichever comes first.
5.4.2.4. Let reagent come to room temperature for 15 minutes prior to use. Keep lid on bottle and store in refrigerator when not in use to reduce evaporation.
5.4.3. Star-TEM (recalcifier)
5.4.3.1. Star-TEM reagent is 0.2 mol/L Calcium chloride in pH buffer 7.4 designed as a recalcifying agent in NATEM, EXTEM, and INTEM assays.
5.4.3.2. Store under refrigeration (2-8°C) until manufacturer's expiration date or 8 days after open date, whichever comes first.
5.4.4. Ex-TEM
5.4.4.1. By adding ex-tem to the sample a standardized activation of extrinsic clotting cascade is triggered by the added tissue factor. The sample is recalcified with star-tem. In the thromboelastometric measurement after addition of the reagents to the sample the clotting process is started and continuously monitored by the ROTEM.
5.4.4.2. The Ex-TEM reagent (activator) is used to monitor the coagulation process via the extrinsic pathway.
5.4.4.3. Ex-TEM is a tissue factor and phospholipids.
5.4.4.4. Store 2-8°C until manufacturer's expiration date or 8 days after open date.
5.4.5. Ap-TEM
5.4.5.1. The Ap-TEM reagent is used to monitor clot firmness after blocking hyperfibrinolysis by aprotinin. The ap-tem reagent is always used in conjunction with ex-tem reagent.
5.4.5.2. Ap-TEM reagent (fibrinolysis inhibitor and recalcifier) is aprotinin 0.2 mol/L Calcium chloride in HEPES buffer pH 7.4 and 0.1% sodium azide, Ap-TEM is ready for use.
5.4.5.3. Store 2-8°C until manufacturer's expiration date or 14 days after open date.
5.4.6. Fib-TEM
5.4.6.1. The Fib-TEM reagent (thrombocyte inhibitor and recalcifier) monitors the clot firmness and is always used in conjunction with EXTEM.
5.4.6.2. Fib-TEM reagent is cytochalasin D/DMSO solution 0.2 mol/L Calcium chloride in HEPES buffer pH 7.4, Fib-TEM is ready for use.
5.4.6.3. Store 2-8°C until manufacturer's expiration date or 14 days after open date.
5.4.7. ROTROL N is a quality control material for monitoring accuracy and precision of analysis carried out on the ROTEM.
5.4.7.1. Let the ROTROL N Dil and Lyo vials reach room temperature. Dissolve the contents of the ROTROL N Lyo vial by pouring the contents of the ROTROL N Dil vial into the lyophilisate. A small drop of the diluent remains in the vial. Do not attempt to transfer the diluent with a pipette. Close the vial with the rubber cap and the screw cap and swirl gently. Take care that the powder is completely dissolved. Then let stand for 10-15 minutes in the closed container, to allow the plasma to reconstitute. Before use, bring to 37˚C on the temperature controlled work area for 5 minutes and carefully mix again by swirling gently.
5.4.7.2. Reconstituted ROTROL N is stable for 8 hours at 2-8˚C.
5.4.8. ROTROL P is a quality control material for monitoring accuracy and precision of analysis carried out on the ROTEM.
5.4.8.1. The contents of a vial of ROTROL P Lyo must be dissolved by pouring the contents of a vial of ROTROL P Dil into the lyophilisate. A small drop of the diluent remains in the vial. Do not attempt to transfer the diluent with a pipette. Do not use any other diluent than the one supplied. Close the vial with the rubber cap and the screw cap and swirl gently. Take care that the powder is completely dissolved. Then let stand for 30 minutes in the closed container, to allow the plasma to reconstitute. Before use, bring to 37˚C on the temperature controlled work area for 5 minutes and carefully mix again by swirling gently.
5.4.8.2. Reconstituted ROTROL P is stable for 4 hours at 2-8˚C.
5.4.9. New QC lots are tested once for acceptability. Data is stored on the L Drive.

6. **SPECIAL SAFETY PRECAUTIONS:**

6.1. The ROTEM *delta* performs at an optimal temperature range of 15-30 °C and storage temperature of 0-50°C. Relative humidity range must be within 20%-85%. The temperature and humidity are recorded each day testing is in operation on a log. The logs are stored in Perfusion and Respiratory Therapy and are reviewed monthly.

6.1.1. If a minimum/maximum thermometer is used to perform continuous monitoring of temperature between daily temperature readings or following a laboratory downtime) e.g. laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.

6.2. Personal protective equipment: always use laboratory coat, gloves and eye/face protection when handling specimens.

6.3. Adhere to all electrical hazards and warnings: keep equipment dry, use only original accessories, do not leave the equipment unattended; service or repairs must be performed by qualified service personnel.

6.4. DO NOT USE EQUIPMENT IF DAMAGED.

6.5. Do not allow liquid to come in contact with the instrument.

6.6. Do not put anything in the couplings unless the packages insert states to do so.

6.7. Do not use near heat source.

7. CALIBRATION/PROGRAMMING/MAINTENANCE

7.1. The ROTEM *delta* has a built in self-monitoring system that performs self-calibration.

7.1.1. Only a calibrated eLine pipette may be used with the ROTEM system.

7.1.2. Every 6-12 months the eLine pipette must be checked for accuracy and precision. The pipette is sent to an authorized service station; contact Instrumentation Laboratory (IL) for specific details.

7.2. Maintenance

7.2.1. Daily Maintenance

7.2.1.1. Clean and disinfect the outer surface of the ROTEM with a lint free cloth or wipe.

7.2.1.2. Clean and disinfect the cup holder with a lint free cloth soaked with disinfectant.

7.2.1.3. Clean the pipette with a damp lint free cloth or wipe.

7.2.1.4. Replace the filter if contaminated with blood.

7.2.2. Weekly Maintenance

7.2.2.1. Replace the pipette filter at least once per week or whenever visibly soiled.

7.2.2.2. Back up the data.

7.2.3. Quarterly Maintenance (every three months)

7.2.3.1. The device temperature and CCD chip values must be evaluated.

7.2.3.1.a Control of the device temperature.

7.2.3.1.b. Turn on the ROTEM system.

7.2.3.1.c. Remove the pins and cups from the axes.

7.2.3.1.d Wait until the ROTEM reaches operating temperature (approx. 5 min).

7.2.3.1.e Open menu service > settings.

7.2.3.1.f. Make a note of the temperature for all four channels. Temperatures should be between 36.0°C and 38°C.

7.2.3.2 Control of CCD chip values.

7.2.3.2.a Open menu service > settings.

7.2.3.2.b Wait for 3 minutes in order to balance the service values.

7.2.3.2.c Take a note of the values for amplitude, center and variance.

7.2.4 Semi-annual Maintenance(every 6 months)(or every 250 measurements)

7.2.4.1 Replace the pin remover .

7.2.4.1.a Push the flat part of the MC Rod into the opening at the lower side of the cup holder.

7.2.4.1.b Insert the sealing tongue deep into the central opening of the cup holder.

7.2.4.1.c Press the springs left and right at the pin remover carefully into their guides.

7.2.4.1.d Press the pin remover until it clicks and the springs slide into their final position.

7.2.4.1.e Yearly maintenance is performed by authorized service personnel.

7.2.5 Tri-Annual maintenance
7.2.5.1 The internal hard disk should be exchanged every 3 years by authorized service personnel.
7.2.6 Maintenance of the ROTEM electronic eLine pipette.
7.2.6.1 Refer to the maintenance schedule for the maintenance of the eLine pipette.
7.2.6.2 Accuracy must be checked after the maintenance of the pipette. If accuracy is not possible, two control measurements must be performed with the ROTROL N. Results must lie within the specified ranges.
7.2.6.3 Maintenance is documented on a log, the log is reviewed monthly by the point of care manager and perfusion manager or respiratory therapy. The log is stored in Perfusion or Respiratory Therapy.

8 QUALITY CONTROL:

8.1 Continuous self-monitoring of temperature is performed when the system power is on.
8.2 The internal controls monitor amplitude, center (location of the amplitude), variance, and temperature must be checked and recorded each day of testing.
8.3 If the internal controls fail, try cleaning the measurement position, then repeat internal controls.
8.4 If internal controls fail again call technical support 1-800-678-0710.
8.5 External quality control:
8.5.1 Perform weekly.
8.5.2 After preventive maintenance.
8.5.3 With a new lot of reagents or QC.
8.5.4 The control ranges vary from lot to lot. The lot number is scanned into the analyzer.
8.5.5 Perform the controls on all 4 channels in a rotating fashion.
8.5.6 The controls are performed like a patient sample, in the QC mode.
8.5.7 The external controls must produce acceptable results before any patient results are reported.
8.5.8 If external QC fails: document corrective action.
8.5.8.1 Repeat measurement on the same channel and a second channel.
8.5.8.2 Perform Internal QC check.
8.5.8.3 If the error does not repeat proceed with testing.
8.5.8.4 If the error repeats, test with fresh controls.
8.5.8.5 If the controls continue to fail call technical support 1-800-678-0710.
8.5.8.6 If the external control fails one channel and not the second channel, do not use the channel that failed and call technical support.
8.5.9 The QC results are downloaded into Telcor.
8.5.10 The QC data is reviewed for outliers. Any outliers are investigated.
8.5.10.1 QC results are reviewed monthly by the point of care manager and coagulation division director.

9 TEST PROCEDURE:

9.1 The ROTEM can be powered on or shut down by using the on/off switch on the right side of the machine.
9.2 Insert a measuring cell onto the instrument. Push the pin up onto the pin axis gently, but firmly ensuring the cup is retained on the axis securely.
9.3 Insert the cup into a preheated cup holder and press in place using the MC Rod Pro. Repeat for the other channels.
9.4 Properly mix all reagents prior to measurement. Keep the blood sample in the pre-warming station prior to testing.
9.5 Login into the system via the touch screen.
9.6 Select the measurement icon.
9.7 Select one of the four channels by using the touch screen.
9.8 Input the name of the test for the channel and scan the label to input patient demographics.
9.9 Repeat for each of the other channels. Data can be copy and pasted.
9.10 When all data has been entered, select the test channel and press the start button.
9.11 Place a clean pipette tip onto the pipette.
9.12 Press the blue start button on the pipette.
9.13 Follow the on-screen instructions for all further pipetting specific to the tests being analyzed.

9.14 Add reagents to the cup.
9.15 After gentle mixing, pipette the blood sample. Ensure there are no air bubbles in the sample.
9.16 Dispense the blood sample into the same reaction cup the reagents were previously placed. Leave the pipette tip in the cup.
9.17 Mix the sample and reagent by aspirating a 300 µl volume into the pipette once and slowly dispensing it.
9.18 After mixing is completed, remove the pipette tip and discard.
9.19 The display screen will indicate that the test has commenced and will give a time period within which the sample chamber must be fitted onto the appropriate channel.
9.20 Carefully place the cup onto the selected channel.
9.21 Press start on the analyzer.
9.22 More than one channel is used per sample; all channels can be viewed at once on the touch screen.
9.23 The tests can be stopped by touching an individual test and pressing the Stop Channel button. Once the measurement has stopped, press the Save and Clear button to make the channel active again.
9.24 Remove the cup holder after the measurement has stopped and discard.
9.25 Results are automatically saved in the database and downloaded into Telcor.

10 CORRELATIONS: See POC Quality Management Policy.

11 CALCULATIONS: Not Applicable

12 REPORTING RESULTS:

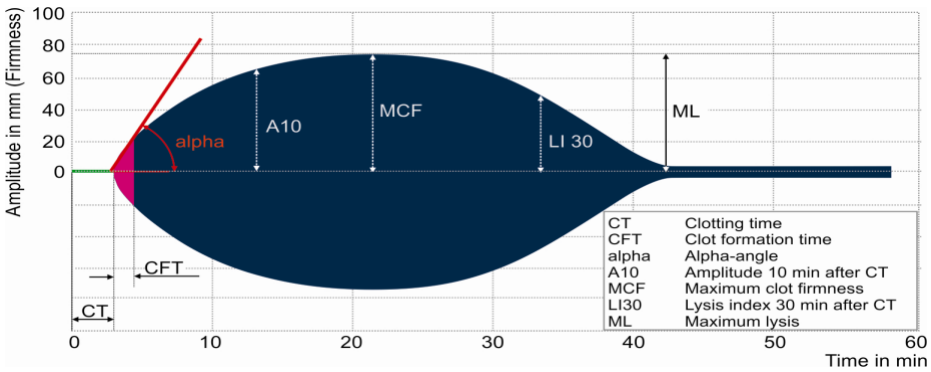
12.1 Reporting of results
- 12.1.1 Report all test results to the ordering physician or authorized person in a timely manner. Results are reviewed at the patient bedside.
- 12.1.2 The ordering physician reviews all results and correlates with the clinical condition.
- 12.1.3 Do not report patient results when QC is unacceptable or has not been run.
- 12.1.4 Patient results are transmitted via Telcor to the patients chart. In the event of a downtime results are stored in the ROTEM and will transmit when the system is up and running.

12.2 Refer to the master listing chart for reference intervals; OneSource Guide to laboratory services.
12.3 Refer to master listing chart for Analytical measurement range (technical range); OneSource Guide to laboratory services.
12.4 Refer to master listing chart for reportable range (CRR); OneSource Guide to laboratory services.
12.5 Refer to Critical Result / Critical Value policy for critical values; OneSource Guide to laboratory services.

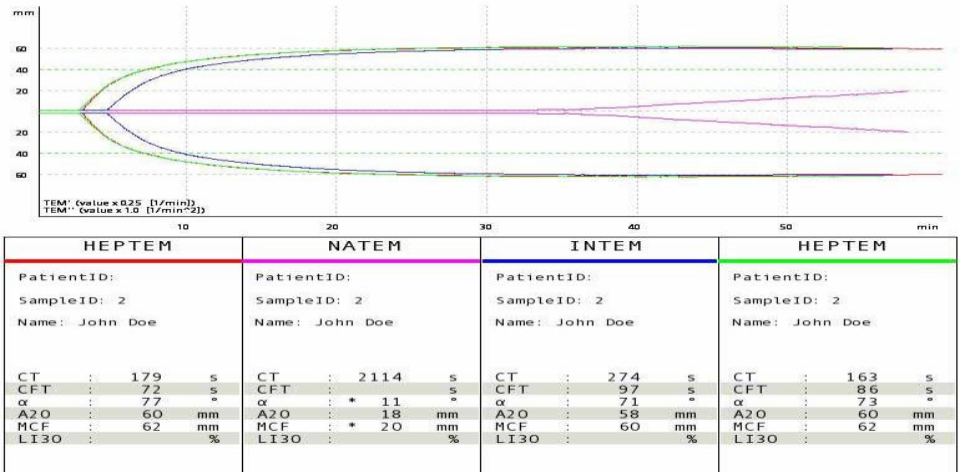
13 INTERPRETATION OF RESULTS

13.1 The ROTEM *delta* is designed to assist in the assessment of a patient's clinical hemostasis by analyzing the following parameters: CT, CFT, α Angle, MCF, A20, LI and ML.
- 13.1.1 **CT (Clotting Time) -** The time from the start of the test until first significant levels of a clot are detected. The CT describes how rapid fibrin formation starts. The CT parameter facilitates the decision to substitute clotting factors such as FFP or thawed plasma.
- 13.1.2 **CFT (Clot Formation Time) –** The time from the measurement of CT until a fixed level of clot firmness. The CFT describes the rate of initial clot formation mediated by thrombin-activated platelets, fibrin and activated factor XIII. The CFT parameter aids in the decision to substitute with platelet concentrate or fibrinogen containing products such as FFP or cryoprecipitate.
- 13.1.3 **α Angle-** The angle between the baseline and the tangent to the clotting curve through the 2mm CT point. The α angle describes the kinetics of the clot formation. This parameter correlates to the CFT parameter. A smaller α angle typically suggests thrombocytopenia or hypofibrinogenemia. A large α angle may be observed in hypercoagulable states.
- 13.1.4 **MCF (Maximum Clot Firmness) -** The amount of platelets and fibrinogen, both the concentration and ability to polymerize.
- 13.1.5 **A 20 (Amplitude at 20 minutes after CT) -** The amount of platelets and fibrinogen, both the concentration and the ability to polymerize as well as factor XIII.
- 13.1.6 **LI (Lysis Index) -** The parameter representing fibrinolysis at a determined time point. It correlates to MCF.
- 13.1.7 **ML (Maximum Lysis) -** Reduction of the clot firmness after MCF in relation to MCF.

13.2 Example:



13.2.1 Sample Patient Report:



14 LIMITATIONS OF THE PROCEDURE:

14.1 Only blood samples collected in 3.2% sodium citrate tubes may be used.
14.2 Not intended for patients under the age of 21.
14.3 Fib-TEM and Ap-TEM assays have not been evaluated for patients with hypofibrinogenemia.
14.4 Fib-TEM has not been tested for patients with dysfibrinogenemia.
14.5 The ROTEM *delta* has the following environmental requirements for use:
14.5.1 Operation temperature should remain between 15°C-30°C.
14.5.2 Relative humidity should remain between 20-80%.
14.6 Results from the ROTEM *delta* should not be the sole basis for a patient diagnosis; the ROTEM results should be considered along with a clinical assessment of the patient's condition and other coagulation tests.

15 REFERENCES:

15.1 ROTEM® *delta* Whole Blood Hemostasis System using Thromboelastometry Operating Manual, March 2012.

16 RELATED DOCUMENTS:

16.1 Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms.