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Procedure: Thromboelastograph (TEG®) Hemostasis System

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NOTE: Format for Standard Transfusion Medicine Procedure not followed to maintain standardization with TEG procedure in Thrombosis and Hemostasis Laboratory.

I. PRINCIPLE/PURPOSE

The Thromboelastograph®(TEG®) System is designed to perform a whole blood coagulation test that produces a hemostasis profile. It automatically records the viscoelastic changes in a sample of whole blood, plasma or platelet-rich plasma as the sample clots, retracts and/or lysis. The resultant profile is a measure of the kinetics of clot formation and dissolution of clot quality. Because the TEG® system monitors shear elasticity, it is sensitive to all the interacting cellular and plasma components in the blood that may affect the rate or structure of a clotting sample and its breakdown.

The TEG® system measures, *in vitro*, the kinetics of the clot formation and dissolution by a mechanical process that monitors very low shear elasticity changes. The TEG measures the clot's physical property by the use of a special cylindrical cup that holds the blood and is oscillated through an angle of 4º45'. A pin is suspended in the blood by a torsion wire and is monitored for motion. The torque of the rotating cup is transmitted to the immersed pin only after fibrin-platelet bonding has linked the cup and pin together. The strength of these fibrin-platelet bonds affects the magnitude of the pin motion. The magnitude of the pin motion is directly related to the strength of the formed clot. As the clot retracts or lyses, these bonds are broken, and the transfer of cup motion is diminished. The rotation movement of the pin is converted by a mechanical- electrical transducer to an electrical signal monitored by a computer.

To evaluate the information displayed by the graphic output, the main parameters of clot formation that are measured include:

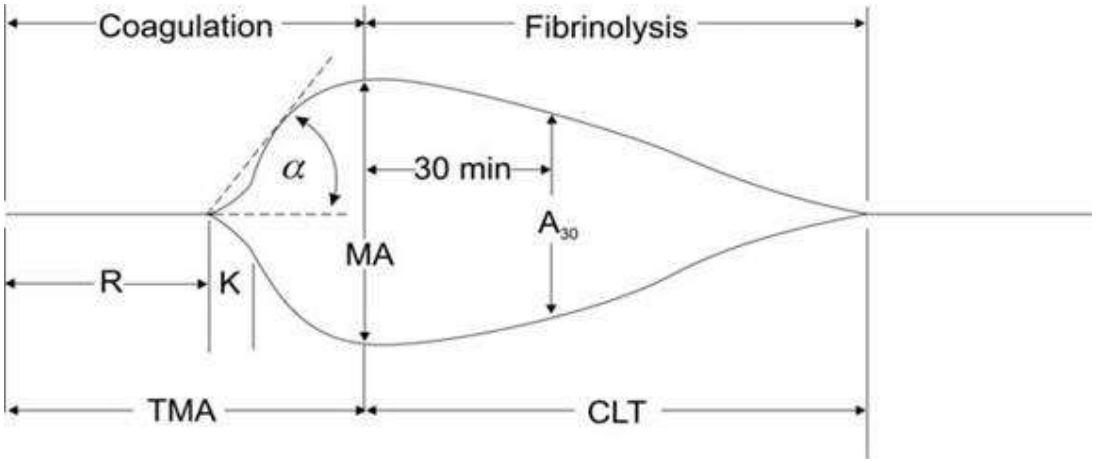
A. **R**: The time from when the sample is put into the TEG until the first sign of clot formation (amplitude of 2mm) is reached.

B. **K:** The time from the R, or beginning of clot formation, to a fixed level of clot firmness (amplitude of 20mm) is reached.

C. **Angle (α):** The rate of clot growth.

D. **MA (Maximum Amplitude):** Maximum strength or stiffness (maximum shear modulus) of the developed clot. MA measures the strength of the clot.

E. **CI:** These four main clotting parameters are combined to yield an index of coagulability (CI) that describes the patient's overall coagulation state.



F. The tracings from the PlateletMapping assay demonstrate a patient's hemostatic balance and their response to antiplatelet therapy. The PlateletMapping assay measures the presence of platelet-inhibiting drugs using:

- Heparin to suppress thrombin
- ActivatorF to replace thrombin in converting fibrinogen to fibrin
- ADP and/or arachidonic acid (AA) platelet agonists.

A standard kaolin-activated aliquot is analyzed to measure total possible platelet activation. A heparinized sample is then split and one aliquot containing only ActivatorF is run to yield an MA that is an expression of fibrin only. Another aliquot measures platelets activated without thrombin and with the addition of ADP or AA plus ActivatorF. The presence of platelet inhibiting drugs is reflected in a reduction of MA values and platelet inhibition is a derived percentage based on MA without activating agents. It is computed separately for ADP and AA (TxA2-receptor) inhibition and represents the contribution of platelets not inhibited by the platelet-inhibiting drugs.

II. SPECIMEN REQUIREMENTS

A. PATIENT PREPARATION: N/A

B. SPECIMEN TYPE

1. For TEG ONLY: **One, 2.7mL or 1.8 mL Na Citrate tube.** Blood must be drawn using 3.2% plastic sodium citrate 2.7 mL or 1.8 mL draw tube size. Tubes must be filled to at least the minimum fill indicator line.
2. For Platelet Mapping: One, 6 mL Na Heparin tube and one, 2.7mL or 1.8 mL Na Citrate tube. Blood must be drawn using 3.2% plastic sodium citrate 2.7 mL or 1.8 mL tube size filled to at least the minimum fill indicator line. Both tubes are required for platelet mapping.
3. Venipuncture should be performed using a 21G or larger needle. Do not shake tube. Mix gently 3-4 times.
4. The specimen tube must come to the laboratory labeled. The label must contain the patient's name, date of birth, hospital number, date and time drawn, and phlebotomist's identification.
5. Samples may be sent through the tube system.
6. Samples may be accompanied by a completed TEG requisition or the test may be ordered in Cerner. See attachment 1 for an example.

C. SPECIMEN VOLUME

1. The tubes drawn (2.7 mL or 1.8 mL) must be full, at least to the minimum fill line. The 6 mL heparin tube must be at least two thirds full.

D. SPECIMEN HANDLING and STORAGE

1. SPECIAL TIMING CONSIDERATIONS

   a. Left undisturbed, samples are stable for up to 2 hours at room temperature.

   b. Samples must be run at least 15 minutes after collection but no more than 120 minutes post collection.

2. SPECIAL TRANSPORTATION NEEDS

   a. Under no circumstances should samples be tested that have been frozen or refrigerated.

   b. These specimens **should not** be sent on ice or centrifuged.

E. SPECIMEN REJECTION CRITERIA

1. When a specimen is rejected, cancel the test(s) charged by choosing a cancel reason from the drop down box located in Department Order Entry (DOE).
   Cancel and contact the ward to request a new sample. The following conditions are causes for rejection:

   a. Specimen is clotted. Choose "Clotted, repeat request."

   b. Specimen is drawn in any anticoagulant other than 3.2% sodium citrate. Choose "Improper contn/repeat request."

   c. Specimen was sent on ice and/or is greater than 2 hours old. Choose "Invalid Specimen".

   d. Tube is underfilled. Improper filling disrupts the 9:1 blood to anticoagulant ratio required for coagulation testing. Choose "Tube underfilled repeat request."

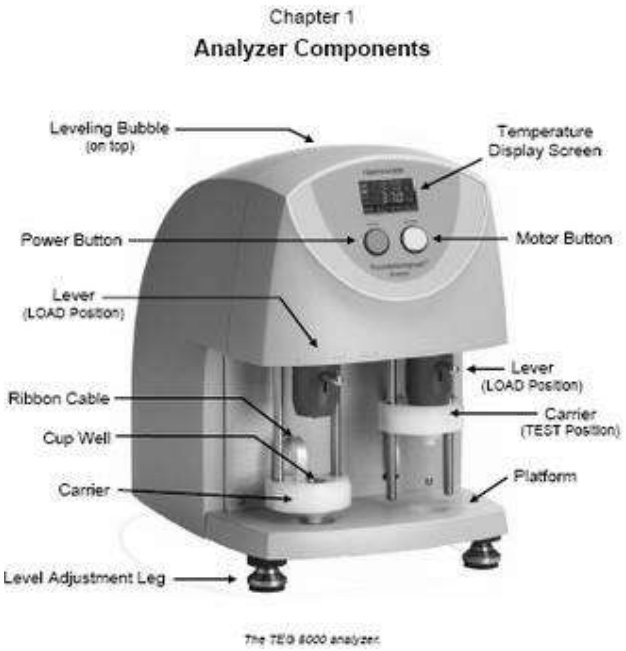
   e. Specimen has platelet clumps. Choose "Invalid Specimen." Specimen was centrifuged. Choose "Lab error ward notified."

2. While in cancel mode, click on the note pad and paperclip icon on the toolbar. Enter who was called regarding the cancel and at what time.

III. EQUIPMENT/REAGENTS/SUPPLIES

A. EQUIPMENT

1. TEG® Analyzer



The TEG 5000 analyzer

2. Pipettes and tips
    a. 50 µL
    b. 10 – 100 µL adjustable
    c. 100-1000 µL adjustable

B. REAGENTS

1. STORAGE
    a. **TEG® Biological Controls-Level I and II**: Animal citrated whole blood including platelet and plasma, stabilizers and buffer. Store at 2-8°C. *Reconstitution:*
        1. Allow each vial to equilibrate to room temperature for 15 minutes.
        2. Tap vial to ensure that reagent is at bottom of vial.
        3. Pour or pipette entire contents of one vial of reagent water included with controls.
        4. Screw cap on and shake vial vigorously and then let it stand, inverted for 5 minutes at room temperature.
        5. After 5 minutes, shake vigorously a second time and let stand for 5 minutes with vial right side up.
    b. **Calcium Chloride (0.2M):** Store at 2-8°C.
    c. **Kaolin Vial**: Standardized reagent consisting of kaolin and buffer. Store at 2-8°C. *Reconstitution:*
        1. Pipette exactly 1 mL of whole blood from a well mixed Na Citrate tube, allowing the blood to run down the sides of the vial.
        2. Re-cap the vial and mix 5 times by a gentle back and forth motion. **DO NOT SHAKE THE VIAL.**
    d. **Activator F (Vial A-P1)**: Lyophilized activator replacing thrombin. *Reconstitution:*
        1. Allow vial to equilibrate to room temperature for 15 minutes.
        2. Tap vial to ensure material is at the bottom of the vial.
        3. Pipette exactly 50 µL of reagent water in to vial. Re-cap and swirl on counter allowing to stand until completely reconstituted.
    e. **ADP (Vial ADP-P2):** Lyophilized ADP, final concentration 2um. *Reconstitution:*
        1. Allow vial to equilibrate to room temperature for 15 minutes.
        2. Tap vial to ensure material is at the bottom of the vial.
        3. Pipette exactly 100 µL of reagent water in to vial. Re-cap and swirl on counter allowing to stand until completely reconstituted.
    f. **Arachidonic Acid (Vial AA-P3):** Lyophilized AA, final concentration 1mM. *Reconstitution:*
        1. Allow vial to equilibrate to room temperature for 15 minutes.
        2. Tap vial to ensure material is at the bottom of the vial.
        3. Pipette exactly 100 µL of reagent water in to vial.
        4. Re-cap and swirl on counter allowing to stand until completely reconstituted.
    g. **Functional Fibrinogen Reagent**: Lyophilized tissue factor with platelet inhibitor.

Reconstitution:

i. Allow vial to equilibrate to room temperature for 15 minutes.

ii. Tap vial to ensure material is at the bottom of the vial.

iii. Pipette exactly 500 µL of blood from **heparin** tube into vial. Re-cap and swirl to mix.

h. **Disposable Cups and Pins, Plain**: Store covered at room temperature until used.

i. **Disposable Heparinase I Cups and Pins, 2 IU**: Disposable, blue cups containing 2 IU of lyophilized Heparinase I, isolated from Flavobacterium heparinum. The amount of enzyme in each cup should be enough to reverse 6 IU of heparin/mL of blood. Store at 2-8ºC in original container.

2. STABILITY

a. **TEG® Biological Controls-Level I and II**: Unopened vials are stable until expiration date. Reconstituted vials are stable for 2 hours at room temperature.

b. **Calcium Chloride (0.2M):** Stable until expiration date on vial.

c. **Kaolin Vial**: Unopened vials are stable until expiration date. Use immediately after reaching room temperature.

d. **Activator F:** Unopened vials are stable until expiration date. Reconstituted vials are stable for 1 hour at room temperature.

e. **ADP:** Unopened vials are stable until expiration date. Reconstituted vials are stable for 1 hour at room temperature.

f. **Arachidonic Acid (AA):** Unopened vials are stable until expiration date. Reconstituted vials are stable for 1 hour at room temperature. **Note: A yellow color may indicate oxidation has occurred. Discard and obtain a new reagent vial. Oxidized reagents can produce inaccurate results.**

g. **Functional Fibrinogen Reagent:** Unopened vials are stable until expiration date.

h. **Disposable Cups and Pins, Plain:** Cups and pins are stable at room temperature, covered until used.

i. **Disposable Heparinase I Cups and Pins, 2IU:** Cups and pins are stable refrigerated (2-8ºC) and sealed in original container until used.

C. SPECIAL SUPPLIES

1. EXAM GLOVES
2. EYE/FACE PROTECTION (required when handling open liquids)
3. IMPERMEABLE LAB COAT

D. SAFETY ISSUES

FOLLOW BIOHAZARD AND CHEMICAL SAFETY POLICIES AS DEFINED IN THE PATHOLOGY SAFETY PROGRAM.

1. REAGENT DISPOSAL: Dispose of used cups and pins in biohazard buckets.

IV. CALIBRATION/VERIFICATION

N/A

V. QUALITY CONTROL

A. QC MATERIALS (refer to the REAGENTS section for details)

1. TEG® Biological Control, Level I
2. TEG® Biological Control, Level II

B. FREQUENCY: All maintenance tasks and QC must be run on every active channel each 8 hours of patient testing. Record results of QC testing on form TEG QC and Maintenance Log . An e-test must be run before each QC. See section XII. Maintenance.

1. Prepare QC according to the steps in the reagent section. Allow QC to equilibrate after reconstitution.
2. Turn on TEG analyzer, using green power button and computer. Allow the temperature of all active columns to reach 37ºC (See Maintenance section, XII., for details).

   a. Double click on the TEG icon on the Windows desktop to enter the software.

The TEG analyzer icon.

   b. After the program loads, a dialogue sign in box will appear. Select the user name "Lab User" from the dropdown box and type in **teg**., then click OK.

   c. A Logon box will appear in the upper left corner of the screen. Select user name (highlight), enter unique password and click on Logon or press Enter.

3. An e-test must be performed before each QC testing.

   a. Select options from the tool bar, then Maintenance

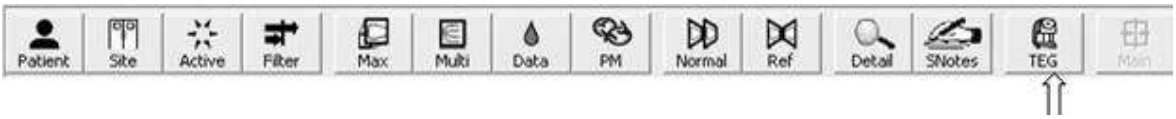
   b. An eTest verifies and maintains the electronic functioning of the analyzer.

   c. Move all active channel levers to TEST.

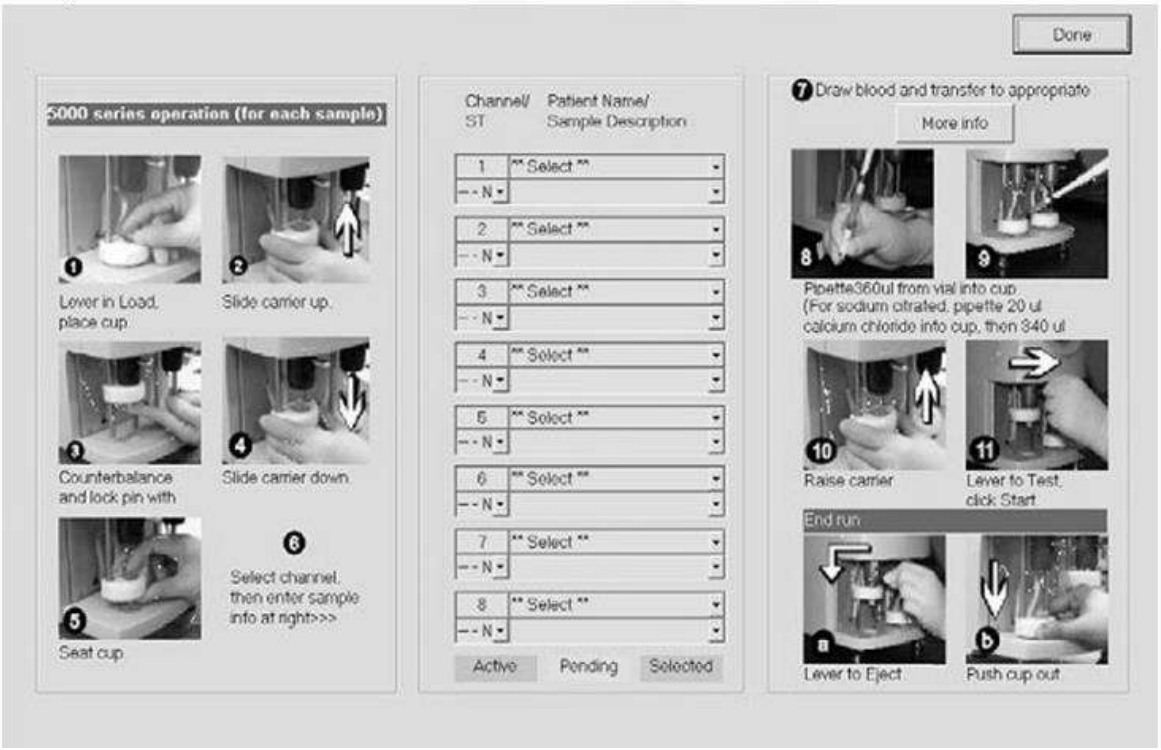
   d. Highlight all active channels and click the eTest button.

   e. The eTest values will be displayed in the Maintenance dialogue box.

4. Do not perform QC or patient testing if eTest fails. See Maintenance section, XII, for troubleshooting details.
5. Once eTest has passed, QC must be run for all active channels. You must be in the TEG screen to run QC/patient samples. Click on the TEG icon in the tool bar.



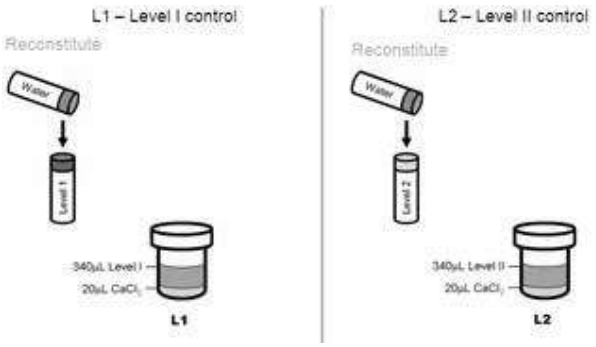
6. The TEG screen shows the sample ID information for all available TEG channels in ascending order. **NOTE:** Available channels are highlighted in yellow, active(running) are green and currently selected are blue.



7. Select the channel by clicking in the sample type area for that channel. Select sample type Level I or II. Use the "name" field to select the lot number of control. "Sample description" field will stay empty. Repeat for all channels used for QC testing. Level I and II must be run on all active channels.

NOTE: Re-select channel one before adding $CaCl_2$ and QC.

8. With lever in the LOAD position, slide the white carrier halfway down the platform.
9. Put a disposable cup and pin and place in the cup well. (DO NOT TOUCH THE OUTSIDE OF THE PIN OR THE INSIDE OF THE CUP).
10. Carefully slide the white carrier all the way up, being sure that the disposable pin is standing straight up in the cup so that the skewer tip can enter smoothly.
11. Push the pin firmly in place using the plastic pusher located at the bottom of the white carrier. Counterbalance the analyzer by putting your hand on top of the analyzer.
12. Slide the white carrier halfway back down and push the cup firmly into the cup well.
13. Pipette 20µL of $CaCl_2$ in to the back and bottom of the cup paying close attention to not touch the sides of the cup. Blow out the $CaCl_2$ in to cup.



14. Select channel 1 and pipette 340µL of Level I or II in to the cup in channel 1. Do not blow out the QC. Immediately slide the carrier up, move the lever to TEST and activate the channel by pushing **F10** on the keyboard. The channel will turn green and the curser will move to the next channel.
15. Repeat for each channel. Click on Done to go the Main screen. Run until the MA is finalized (no astericks).
16. Stop by pressing **F11** on the keyboard. The stopped channel will turn to white. NOTE: Do not remove a sample from the analyzer before it is terminated on the computer. Software is still calculating values and this may cause spurious results.
17. Unload cups and pins by moving the levers to LOAD position and pulling down to eject the pin. Slide the carrier down to the platform and press firmly so that the plastic pusher at the bottom of the carrier pushes the cup out of the well.
18. Dispose used cups in biohazard buckets. If QC is out of range, no patient samples can be run until resolved.

C. Acceptable Limits

1. Active QC lot ranges are entered into the data base. QC that fails will have asterisks around the parameter.
   An action text box appears to write what action was taken. Action steps include but not limited to:
   a. Check temperatures, eTest and level.
   b. Ensure correct lot numbers of QC being used are in date.
   c. Reconstitute new QC material and repeat QC. If still out of range, call Haemonetics hot line at 1-800-438-2834 for assistance.
2. Evaluate the data for out-of-range values, bias and trending. Document any QC actions in the Action log and indicate what corrective actions were taken.
3. Actions include but not limited to:
   a. preparing new QC material
   b. checking the test system components such as temperature, level, etc. See Maintenance section, XII., for details.
4. The QC run is acceptable if three out of four parameters (R, K, α, and MA) for Level I are within QC ranges established by the laboratory and three out of three parameters for Level II.
5. Verify each channel's results in the Max screen to see the established QC ranges.

VI. ASSAY PROCEDURE

A. INSTRUMENT PREPARATION: Level the TEG analyzer and perform an e-test when necessary. See QC frequency section and the Maintenance section, XII, for details.

B. REAGENT PREPARATION:

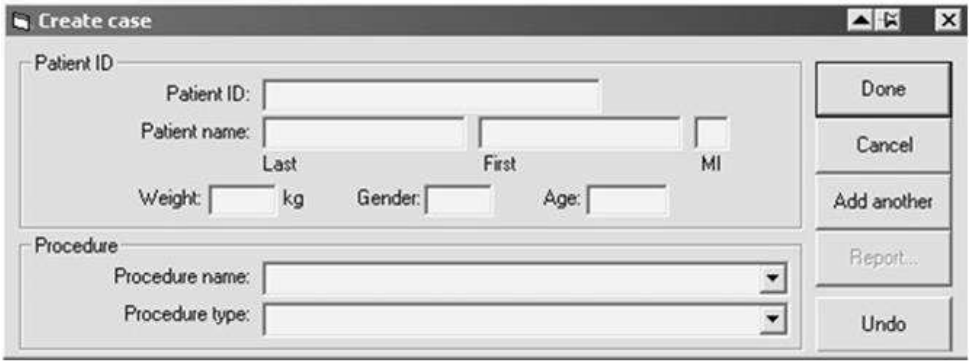
1. Remove all reagents from refrigerator and allow to come to room temperature.
2. Remove QC material, if not already run, and prepare as outlined in the reagent section.

C. PATIENT SAMPLING (CK and CKH):

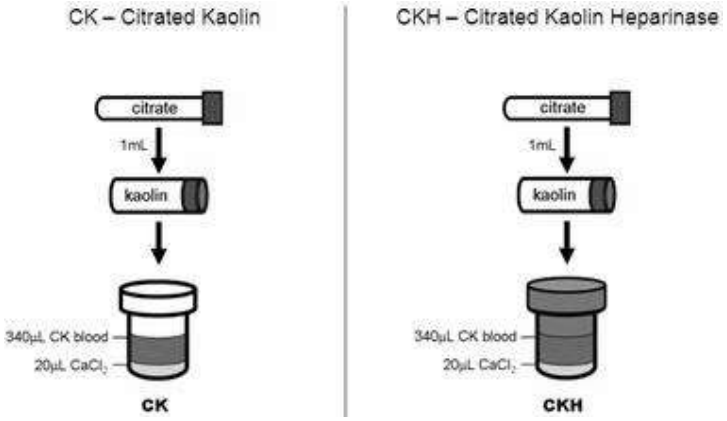
1. **BEFORE PATIENT SAMPLES CAN BE RUN, E-TEST MUST BE RUN AND PASSED AND ALL QC ISSUES MUST BE RESOLVED.**

2. Select the TEG icon from the tool bar and select the channel(s) to be used. Select the sample type from the drop down menu. Choices are:
   a. **CK**-citrated sample with kaolin
   b. **CKH**-citrated kaolin with heparinase (requires blue heparinase cup).
3. Select a patient name from the drop down box. If this is the first time a patient is being run, a new case must be added.
   a. Select the "Case" icon from the main toolbar.

   b. Enter the patient's MRN, first and last name in the appropriate fields.



   c. Select Done to finish.
4. Follow the instructions in the QC/Frequency section on how to load cups and pins. Place cups in channels to be used.
5. Pipette 20µl of $CaCl_2$ in to the back and bottom of the cup paying close attention to not touch the sides of the cup. Blow out the $CaCl_2$ in to cup.



6. Tap the Kaolin vial to ensure reagent is at the bottom of the vial. Mix the citrated blood several times and then use a transfer pipette to add 1.0 mL of whole blood into the Kaolin vial.
7. Re-cap the vial and mix gently 5 times. Swirl vial so that blood covers all sides of the vial. **DO NOT SHAKE VIAL.**
8. Immediately pipette 340 µL of the Kaolin blood into the back of the cup taking care not to touch sides of cup. Do not blow out and avoid bubbles. Raise the carrier all the way to the top and move lever to **TEST.**
9. Press **F10** on the keyboard to activate the channel. Background should turn green to indicate channel is active.
10. Repeat steps 2-9 for all other channels to be run. Click on Done to go to the Main screen.

11. When running a TEG COMP, the CKH can be discontinued if the R value is one minute or less than the R value of the CK. Only if the patient is on heparin, or heparin has been released as a result of trauma, should there be a significant difference between the R values.
12. If the difference between the R values is greater than one minute, continue to run both tests. Use the shorter R value as the baseline to calculate and result the Platelet Mapping.
    NOTE: Do not remove or stop the remaining TEG sample before the sample is terminated on the computer. Since the software is still calculating values, removal of the sample may cause spurious values to be written to the database.
13. To end a test if not already terminated by the software, press **F11.**
14. Unload cups and pins by moving the levers to LOAD position and pulling down to eject the pin. Slide the carrier down to the platform and press firmly so that the plastic pusher at the bottom of the carrier pushes the cup out of the well.
15. Dispose used cups and pins in the biohazard bucket.
16. Heparinase cups must be used when:
    a. The patient is on heparin.
    b. The sample has been drawn through a line or lock.
    c. There is any chance the sample has been contaminated.
    d. Post protamine administration.
    e. A TEG COMP is ordered.
    f. If the R value for the CK exceeds 11 minutes.

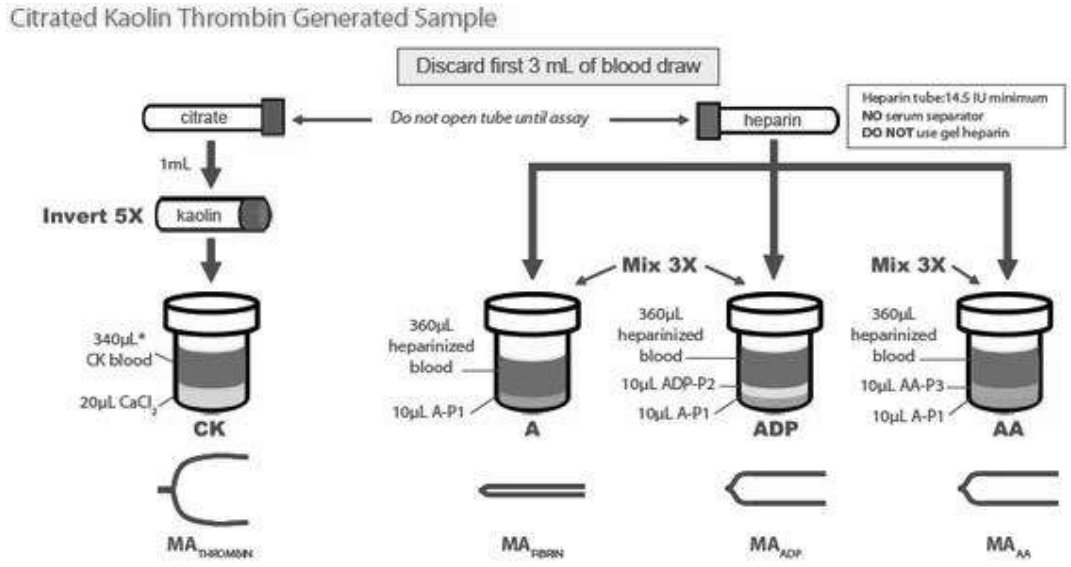
D. PATIENT SAMPLING (PLATELET MAPPING)

1. **BEFORE PATIENT SAMPLES CAN BE RUN, ETEST MUST BE RUN AND PASSED AND ALL QC ISSUES MUST BE RESOLVED.**
2. Select the TEG icon from the tool bar and select the channel to be used. Select the sample type from the drop-down menu. Choices are:
    a. **CK-**citrated sample with kaolin
    b. **CKH-**citrated kaolin with heparinase (requires blue heparinase cup).
    c. **Select CKH if patient is on heparin. Select both if a TEG COMP is Ordered. See section VI. C 11 and 12 for running TEG COMP.**
3. Select a patient name from the drop-down box. If this is the first time a patient is being run, a new case must be added.
    a. Select the "Case" icon from the main toolbar.

    b. Enter the patient's MRN, first and last name in the appropriate fields.
    c. Select Done to finish.
4. Select channel two. Go to **ST** field and select **A-Activated.** Select patient name from the patient name field. Select Sample Description from dropdown menu.

5. Select channel three. Go to **ST** field and select **ADP-Activated +ADP.** Select patient name from the patient name field. **Select Sample Description from dropdown menu.**
6. Select channel four. Go to **ST** field and select **AA-Activated +AA. Select** patient name from the patient name field. Select Sample Description from dropdown menu. Go back up to the first channel.

   and select it when ready to begin testing.
7. Follow the instructions in the QC/Frequency section on how to load cups and pins. Place cups in all four channels. Use a blue heparinase cup for TEG baseline when patient is on heparin.
8. Pipette 20 uL of $CaCl_2$ into the back and bottom of the first cup paying close attention to not touch the sides of the cup. Blow out the $CaCl_2$ into cup.
9. Pipette 10 uL of activator into the back of the cup in channel 2, 3 and 4.
10. Pipette 10 uL of ADP into the back of the cup in channel 3.
11. Pipette 10 uL of AA into the back of the cup in channel 4.
12. Tap the Kaolin vial to ensure reagent is at the bottom of the vial. Mix the citrated blood several times and then use a transfer pipette to add 1.0 mL of whole blood from the Na citrate tube into the Kaolin vial.
13. Re-cap the vial and mix gently 5 times. Swirl vial so that blood covers all sides of the vial. **DO NOT SHAKE VIAL.**
14. Immediately pipette 340 uL of the Kaolin blood into the back of the cup taking care not to touch sides of cup. Do not blow out and avoid bubbles. Raise the carrier all the way to the top and move lever to **TEST.**
15. Press **F10** on the keyboard to activate the channel. Background should turn green to indicate channel is active.
16. Gently invert the heparin tube 5 times to mix. Pipette 360 uL of blood from the heparin tube into the back of channel 2.
17. Gently mix the blood in the cup by pipetting half of the blood in and out three times, avoiding any bubbles.
18. Raise the carrier and move the lever to **TEST. Press F10** to activate the channel. Background turns green.
19. Replace the pipette tip and repeat step 16 for channels 3 and 4.



20. Let testing run until MA is defined for the Activator, ADP-Activated and AA-Activated. To end a test if not already terminated by the software, press **F11.** Return the lever to the **LOAD** position. **NOTE:**

    Growing MA (see Section XI. Limitation of Method Section F), if MA is greater than 25 mm AND Activator test runs for more than 15 minutes, repeat Activator F using Functional Fibrinogen.

21. Slide the carrier down firmly against the platform so that the plastic pusher located at the bottom of the carrier pushes the cup out of the well.

22. Dispose used cups and pins in the biohazard bucket.

23. **Heparinase cups must be used for baseline TEG when:**

    a. The patient is on heparin. See below.

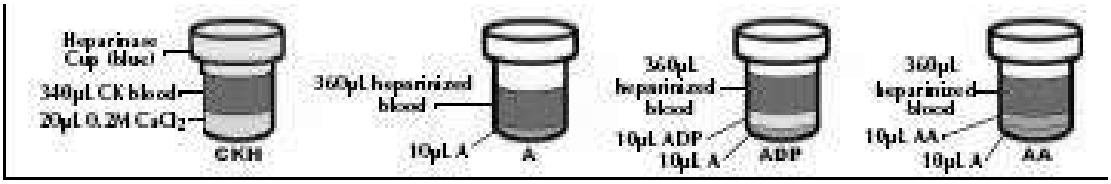
    b. The sample has been drawn through a line or lock.

    c. There is any chance the sample has been contaminated.

    d. Post protamine administration.

    e. The difference between the R values of the CK and CKH is greater than one minute, with the R value of the CKH being the shorter.

    f. If the R value for the CK test exceeds 11 minutes.



VII. METHOD VALIDATION

See method validation under separate cover.

VIII. CALCULATIONS/DATA REDUCTION (PLATELET MAPPING)

Note - calculations are automatically performed by the TEG instrument.

A. The MA value of each assay is used in software calculations to determine platelet function with and without platelet inhibiting drugs. The thrombin induced activation of the blood demonstrates the patient's baseline clot strength due to platelet and fibrin contributions=$\mathbf{MA_{THROMBIN}}$. $\mathbf{MA_{THROMBIN}}$ represents 80% platelet contribution and 20% fibrin contribution.

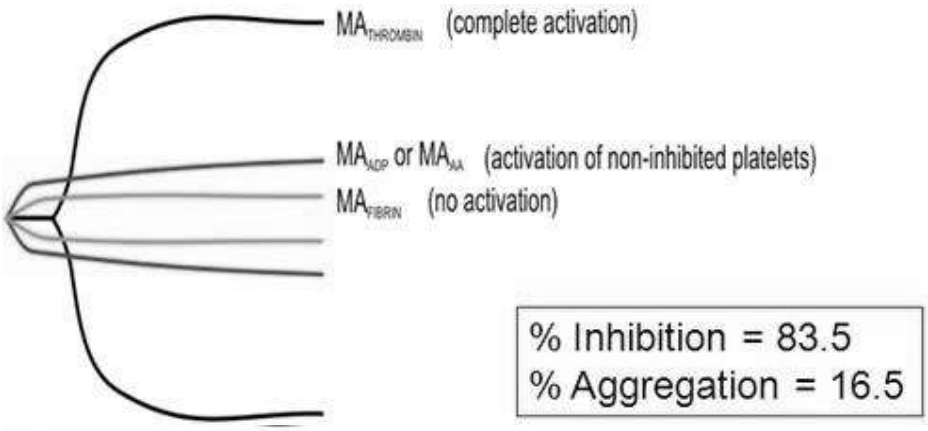
B. To determine only platelet contribution to clot strength the MA value for the activator sample is subtracted from the MA value for the thrombin (baseline) sample since
   $\mathbf{MA_{ACTIVATOR}}$ represents clot strength without platelet contribution or fibrin only.
   $\mathbf{MA_{THROMBIN}}$ **MA**–$_{ACTIVATOR}$ = **Total Baseline Platelet Function MA**

C. The agonist activated tests; ADP or AA show patient agonist induced clot strength and demonstrates ADP or AA inhibition. To assess the platelet contribution in these samples, the MA value for the Activator sample is subtracted from the MA value for the agonist activated sample.

   $\mathbf{MA_{AGONIST}}$ –$\mathbf{MA_{ACTIVATOR}}$ = **MA Contribution Agonist Activated Platelets Only MAADP or AA - MAACTIVATOR**

   %Inhibition=100% --$\frac{\mathbf{MA_{THROMBIN}} - \mathbf{MA_{ACTIVATOR}}}{\text{MAPlatelets Only, ADP or AA}}$

   % Inhibition =$\frac{}{\text{MA Total Platelets}}$



Platelet Mapping Assay

- Measures platelet inhibition along with maximum platelet function as a reference point
- Monitors platelet inhibition at GPIIb/IIIa, ADP, and TxA_2 receptors

IX. REPORTING RESULTS

A. **EXPECTED OR THERAPEUTIC VALUES**

1. EXPECTED VALUES FOR CK and CKH SAMPLES
   a. R Value = 5-11 minutes
   b. K Value = 1-3 minutes
   c. α = 53-73º
   d. MA = 50-72 mm
   e. LY30 = 0-7%
2. Reference ranges are verified periodically by database search, literature search, LIS normal data review, and/or evaluation of normal volunteers.

B. **REPORTING FORMAT CK and CKH**

R and K values are reported in minutes, angle is degrees, MA is mm and LY30 is percent. CI is reported as a negative or positive number.

1. Blood Bank will result all parameters manually.
2. See Job Aid BBT-JA010 for instructions.

C. **REPORTING FORMAT PLATELET MAPPING**

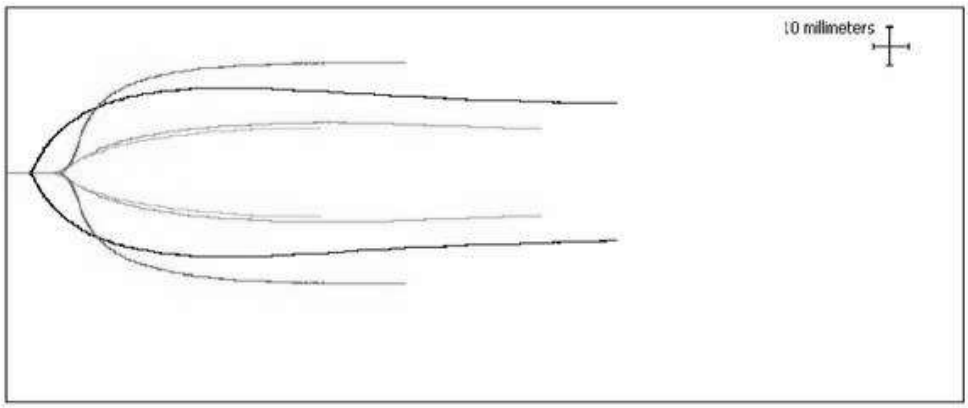
Platelet Mapping results are reported as % inhibition for ADP and/or AA and % aggregation for ADP and/ or AA.

Blood Bank will result all parameters manually.

D. **REPORTABLE RESULTS**

1. The reportable ranges for the TEG parameters are as follows:
   a. **R**: 0-50minutes
   b. **K**: 0->50 minutes
   c. **Angle**: 0-90º
   d. **MA**: 0->90 mm
   e. **LY30**: 0 – 100%

2. Single channel results can be displayed and printed by double clicking on any tracing to enlarge. Click Report to print.
3. To print multiple channels, click the Multi icon then select all desired channels for viewing. Click Done.
    a. The tracings are displayed offset from each other with each tracing in a different color. To view the tracings superimposed on each other, click Super in the toolbar.



Tracings from top to bottom:

Seq	Channel	Patient	ST	Sample description			Operator	Machine SN
1	2	summary, example	K	baseline	7/18/2001	11:47 AM		
2	6	summary, example	K	on pump	7/18/2001	03:23 PM		
3	1	summary, example	K	rewarming	7/18/2001	05:18 PM		
4	6	summary, example	K	post protamine	7/18/2001	06:06 PM		

Seq	Channel	R min	K min	Angle deg	MA mm	CI	PMA	G Kd/so	SF min	EPL %	LY30 %
1	2	3.5	3.4	64.5	44.0	-1.9		3.9	3.1	3.0	3.0
2	6	7.7	12.3	29.5	25.3	-12.4		1.7	6.6	0.6	0.6
3	1	7.7	17.7	29.6	22.5	-14.5		1.5	6.6	*0.0*	*0.0*
4	6	8.1	2.3	69.0	67.3	-2.4		6.6	7.6	*0.0*	*0.0*

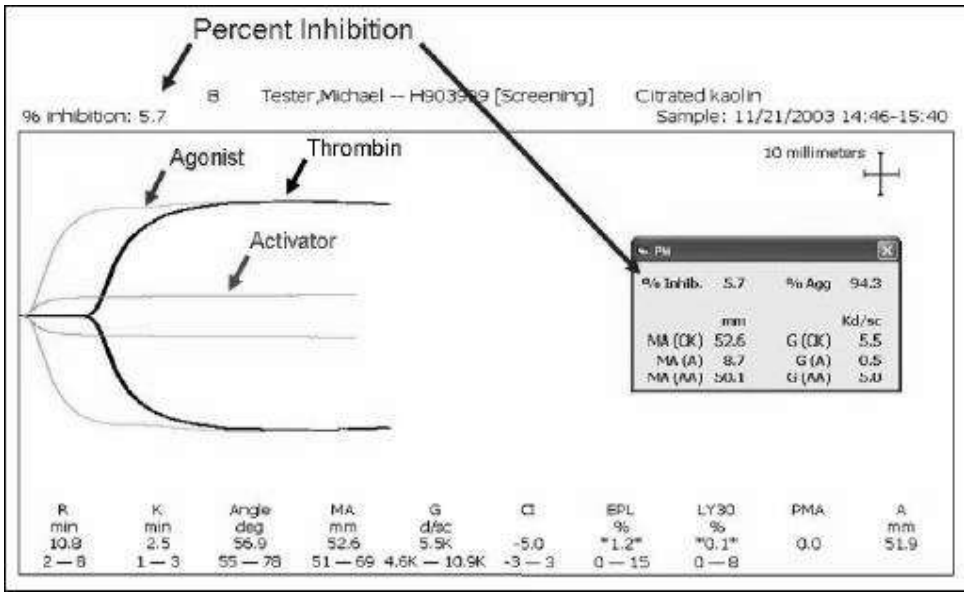
4. PLATELET MAPPING: After the MA for each channel of the platelet mapping tests is defined/ complete **AND** the CK and or CKH is completed, the software is able to calculate and display the percent inhibition and percent aggregation.

    a. Click the Multi icon in the tool bar. 

    b. Select the patient samples in the order below:
        i. CK channel (Use CKH when patient is on heparin). Name as BASELINE.
        ii. Activated Channel
        iii. ADP or AA
        NOTE: You can only select 3 channels at a time. Decide which ADP or AA to calculate first.

    c. Click DONE. 

The software displays the tracing on your screen along with the percent inhibition and percent aggregation. Click **Report** to print. See below for example report.



E. **COMPUTER CODES** See Job Aid TEG/Platelet Mapping Order and Result Entry.

1. Results can be verified by using the ARE function in Cerner.
   a. Enter the ARE function from the appbar..
   b. Enter either the barcode or the accession number. Click Retrieve.
   c. Enter the results for the appropriate DTA's.
   d. Ensure that the entries are accurate then click on Verify at the bottom right of the screen.
   e. If corrections must be made, go to the Correction mode under the Task function on the Appbar.
      i. Select the result to be corrected. Double click on that cell and enter the corrected result.
      ii. Once the result is changed, the only option is to select the Correct key at the bottom right of the screen.
      iii. All corrected results will be tagged as modified.
2. See X., PROCEDURE NOTES, A., CLINICAL INTERPRETATION for additional comments if necessary.

F. **INTERFERENCES:**

1. The TEG may be affected by hemodilution, cardioplegia solutions, hypothermia, platelet dysfunction, hypofibrinogenemia, coagulopathies, and certain medications.
2. It is recommended a discard tube be drawn for TEG sample analysis. Not drawing a discard tube has shown to interfere with the R parameter.
3. Underfilling the Na Citrate tube has shown to interfere with both the R and Angle parameters. It is recommended that the citrate tube always be filled completely by vacuum.
4. Hemolysis has been shown to significantly affect the R parameter. If the R is affected, sample can be spun down to check for hemolysis. Attach a hemolysis comment to the R parameter in Cerner.
5. The presence of a hemodiluted sample has been shown to interfere with both the R parameter and the Angle parameter, beginning at 40% dilution.
6. A flat line or unusual tracing may occur when:
   a. Carriers are not moving
   b. CaCl was not added to the cups

c. The cable connections are loose

d. Heparin is present and a clear cup or a blue cup (heparinase) was used but there is more than 6 IU / mL of heparin in the sample.

e. TEG is not level

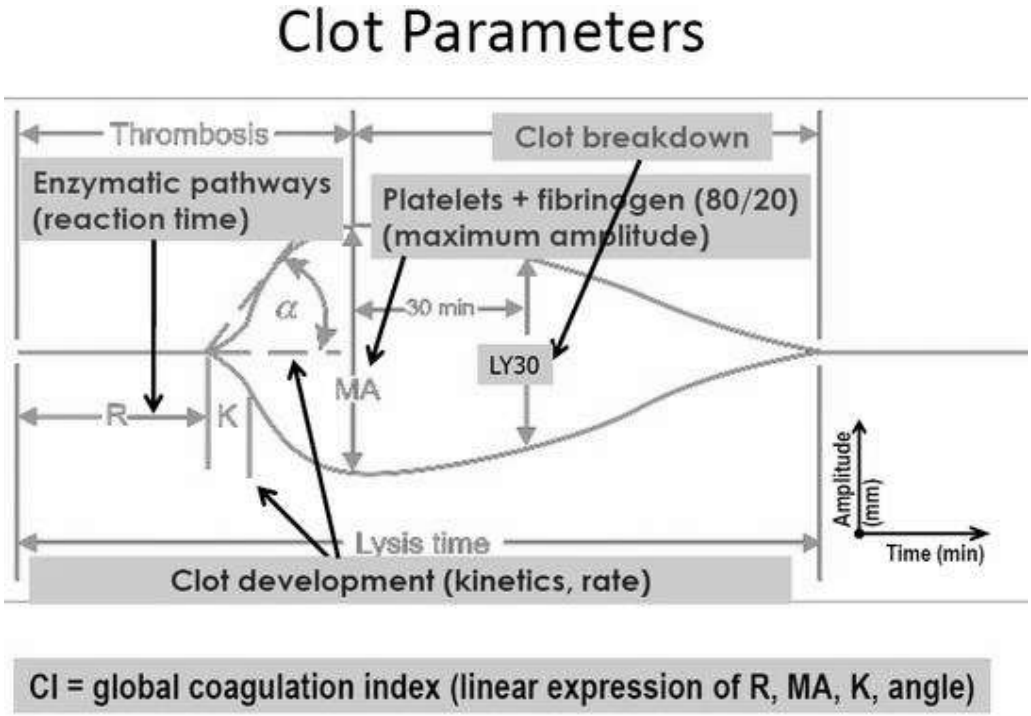
f. The cup and pin were not loaded properly

G. **TURN AROUND TIME/FREQUENCY**
Specimens are accepted 24 / 7. The test must be started within 2 hours of collection.

X. PROCEDURE NOTES

A. CLINICAL INTERPRETATION: Each TEG parameter represents a different aspect of the patient's hemostasis.

1. **R**: The time of latency from the time that the blood was placed in the TEG Analyzer until the initial fibrin formation. R is prolonged by anticoagulants and is shortened by hypercoagulable states.
2. **K:** K is a measure of the speed to reach a clot strength of 20mm.
3. **Angle**: Angle measures the rapidity (kinetics) of fibrin build-up and cross-linking that is the speed of the clot strengthening. The angle is more comprehensive than K and is decreased by anticoagulants that affect fibrinogen and platelet function.
   a. Both K and angle measure similar information and both are affected by the availability of fibrinogen, which determines the rate of clot buildup in the presence of factor XIII, which enables the cross-linking of fibrin to form a stable clot; and to a lesser extent, by platelets.
   b. An elongated K and reduced angle represent a low level of fibrinogen (factor XIII is rarely deficient) and can be corrected by administering cryo of FFP, which have both. K is prolonged by anticoagulants that can affect fibrinogen and platelet function.



CI = global coagulation index (linear expression of R, MA, K, angle)

4. **MA**: A direct function of the maximum dynamic properties of fibrin and platelet bonding via GPIIb/IIIa and represents the ultimate strength of the fibrin clot. MA is affected by platelet number and function and, to a lesser extent, by fibrinogen level.

a. MA represents 80% platelet and 20% fibrinogen involvement.

b. MA and K, angle are correlated due to the interaction between fibrinogen level and platelets which together form the fibrin-platelet bonding to produce the final clot. Therefore, there is a compensated effect between fibrinogen level and platelets.

5. **LY30**: LY30 measures the rate of amplitude reduction 30 minutes after MA and represents the ultimate stability of the clot. LY30 greater than 7.5% represents hyperfibrinolysis.

6. **CI (Coagulation Index):** Linear combination of R, K, angle, and MA. Positive values (CI>+3.0) indicate the sample is hypercoagulable. Negative values (CI<-3.0) indicate that the patient is hypercoagulable.

7. Examine the baseline results from the thrombin generated sample. It is important to assess the underlying hemostasis without the effect of the antiplatelet drug. The kaolin sample does not demonstrate the effect of ADP inhibiting drugs, AA pathway inhibiting drugs and GPIIb/IIIa inhibiting drugs.

8. Look at the % inhibition to determine the agonist-induced platelet activation caused by the agonist (ADP and/or AA).

   a. A **LOW**% inhibition means that there is **little effect** on platelet activation.

   b. A **HIGH**% inhibition indicates that there is a **large effect** on platelet activation.

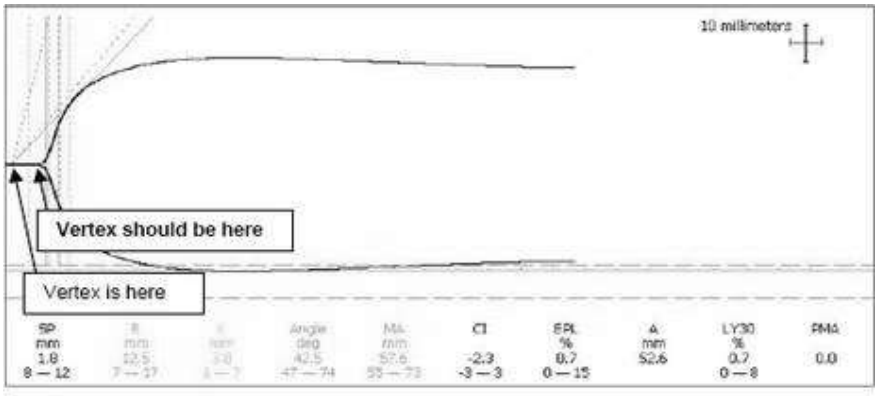
XI. LIMITATIONS OF METHOD

A. Traumatic sampling of blood will reflect the trauma of the phlebotomy and not coagulation of the patient. When using an evacuated tube system, a citrate discard tube must be drawn first. If the blood sample is difficult to draw because the needle is against the wall of the vessel, the endothelium may release plasminogen activators which can cause artifacts on the TEG tracing.

B. Any tracings that do not show the formation of a clot should be considered beyond clinical significance. Obtain a new sample immediately and re-test. Test results should always be evaluated in light of a specific patient's condition or anticoagulant therapy. Any test result exhibiting inconsistency should be repeated or supplemented with other test values.

C. The baseline value of the TEG determines the zero-starting point of the graphical output tracing. Therefore, baseline out of range conditions may prevent the TEG graph from reaching its maximum amplitude. The MA parameter may not reach its maximum value.

D. A double R tracing is often due to a loose pin, or the analyzer is receiving vibrations producing a tracing that has two R lines that are very close together. This results in a lower angle values. Note the position of the vertex of the angle in the tracing below.



An example of a Double R tracing. Note that the line for the angle intersects the R far from the split and produces a lower angle value.

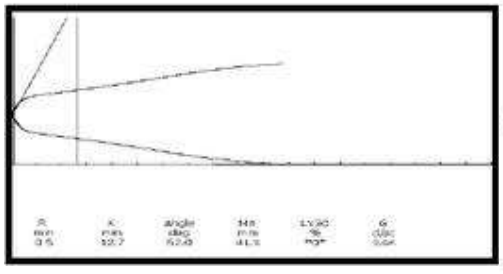
E. If a patient is in primary fibrinolysis, the patient should be treated before performing platelet mapping. Primary fibrinolysis can produce inaccurate results.

F. A growing MA occurs when the MAACTIVATOR tracing continues to grow wider than a normal tracing and fails to level out. The Activator sample is fibrin only. The presence of hyperactive platelets and/or thrombin breakthrough causes binding of platelets to the clot. This can occur in patients with:

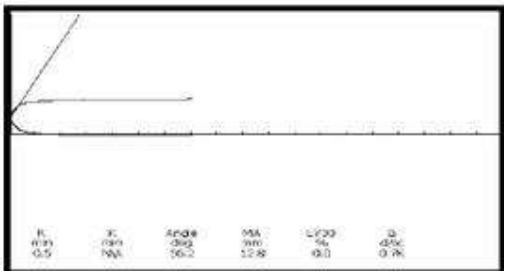
1. Extreme hypercoagulability (elevated fibrinogen levels)
2. Blood exposure to artificial surfaces
3. ATIII deficiency
4. Pregnant women

In such cases, haparanized blood should be pre-treated with functional fibrinogen reagent. Add 500 uL of blood from the heparin tube in to FF vial and swirl to reconstitute. Mix by inversion 5 times. Use this pre- treated blood for the second channel, the **A** cup. Select this MA for the platelet mapping calculation repeat.

Activator Tracing -Growing MA Sample



Activator Tracing – Normal Sample



A. Technical support can be reached at any time by calling 800-GET-A-TEG. Tracings can be faxed to 847-588-0455.

XII.MAINTENANCE

A. DAILY-Assigned Tasks Each Shift

1. **QC is run each 8 hours of patient testing.**
   a. Record results on Form TEG QC and Maintenance Log .
2. **Cleaning the Instrument,** record completion of task on TEG QC and Maintenance Log
   a. Ensure cup wells are clean and dry. If necessary, clean with a cotton swab.
   b. Wipe off outside of TEG analyzer with disinfecting wipes.
3. **Leveling the Analyzer,** record completion of task on TEG QC and Maintenance Log
   a. Level the analyzer if necessary, by adjusting the height of the three legs on the bottom of the TEG while observing the bubble level located on the top of the TEG.
   b. Use the circle on the bubble level as a guide in centering the bubble. The leg height is adjusted by rotating the leg.
   c. TEG must be level at all times to obtain accurate results.
4. **eTEST**, record completion of task on TEG QC and Maintenance Log
   a. An eTest verifies and maintains the electronic functioning of the TEG. Select Options from the tool bar in the TEG screen, then Maintenance.
   b. Move all channel levers to be tested to TEST.

c. Click the eTest button for channel 1. Click the remaining channels. All channels can be tested simultaneously.

d. The eTest values will be displayed in the dialogue box with a pass/fail. The acceptable range is 1800-2300.

NOTE: Do not perform patient testing if unable to obtain "eTest is OK" message.

e. Troubleshooting eTest:

Message	Cause/Remedy
eTest is OK	When the reading is within range, the computer issues this message. The acceptable range is 1800-2300.
Not at equilibrium	This might be due to environmental factors or too much vibration. Repeat eTest. If the message is repeated, the analyzer might be unsteady and should be stabilized.
eTest out of range	Repeat eTest by clicking on "eTest" again. If the message is repeated, do not use that channel for patient testing
eTest off center	The lever is in Load position; move it to Test and click on "eTest" again. The analyzer is not level; uses the bubble level on the top of the analyzer to ensure it is level and click on "eTest" again.

f. If the values in the Min and Max fields are both 2027 or the values do not change when the lever is moved to TEST, it is likely there is no signal present. Check that the cables are connected to the correct inputs and that the connections are secure.

g. Click the DONE button. A pop box appears as a reminder to move all levers NOT running samples back to the LOAD positions. Click OK.

5. **Daily Temperature**

a. Temperatures must be recorded for each channel in use. Temperature display is located on the front panel. Channel 1 (RED) is on top and Channel 2 (GREEN) is on the bottom.

b. Let the analyzer come to temperature. Record the temperatures in the TEG QC and Maintenance log form TEG QC and Maintenance Log. Acceptable temperature is 37º+/-0.5ºC. If temperature is out of range, a temperature test must be performed.

c. See monthly temperature testing procedure below.

6. TEG Manager Verification: Follow instructions on Job Aid: How to Run TEG Manager

B. MONTHLY: Record results on Form TEG QC and Maintenance Log

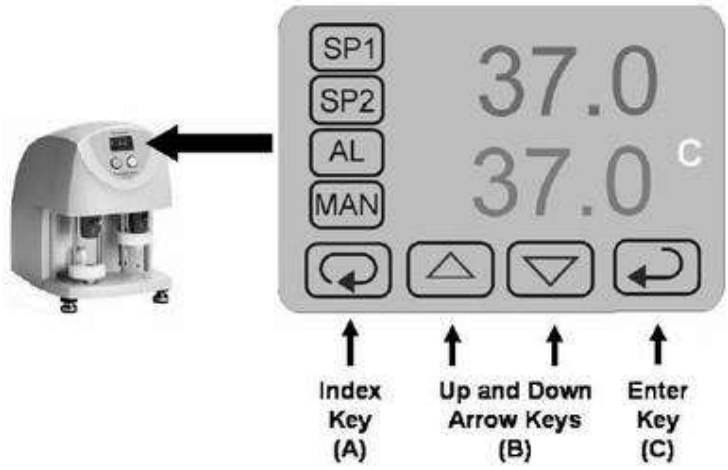
1. **Temperature Test**

a. Place a disposable cup in each cupwell and fill with tap water. Let stand 10 minutes.

b. Insert wire sensor of Fluke 2 thermometer in the water of a

well. Check the temperature of the water allowing sufficient time (approximately 1 minute) for the sensor to equilibrate. The temperature difference between the water and the control display should not exceed +/-0.5ºC.

c. If the temperature is out of range, adjust the Input Offset Correction. Simultaneously press the up arrow and Enter key to access the secondary menu of the temperature controller.



d. If the temperature is out of range for the left carrier, scroll through the menu by pressing the Index key until you reach the display, "InC1". If the temperature is out of range for the carrier on the right, scroll through menu by pressing the Index key until you reach the display, "InC2".

e. To adjust the value of the Input Offset Correction, use the up/down arrow keys.

f. Press the enter key. The display will flash once.

g. Press the Index key until you return to the Main Menu.

h. To set the temperature of the TEG, use the control buttons on the temperature controller.

i. Document on the TEG online maintenance sheet.

j. The Report command button in the Maintenance screen provides a report of all maintenance that was performed. Print out reports as needed for documentation.

XIII. ACTION TO BE TAKEN IF METHOD BECOMES INOPERABLE

A. If TEGs at Riley become inoperable, then TEG testing can be sent to Methodist Blood Bank.

B. If TEGs at Methodist become inoperable, then TEG testing can be sent to Riley Blood Bank.

XIV. REFERENCES

A. TEG® Hemostasis System Level I Control package insert

B. TEG® Hemostasis System Level II Control package insert

C. Disposable Cups and Pins package insert

D. Disposable Cups and Pins Heparinase package insert

E. TEG® Hemostasis System Kaolin

F. TEG® 5000 Operator Training Manual

G. TEG® 5000 Guide to Platelet Mapping Assay

XV. APPENDICES/ADDENDUMS

TEG QC and Maintenance Log

TEG/Platelet Mapping Order and Result Entry

TEG/Platelet Mapping Result Entry

Job Aid: How to Run TEG Manager Attachment 1:TEG request and instructions

PROCEDURE

BBT-019