

## TEG testing by TEG 5000

### Principle

The TEG® Instrument System records the process of blood coagulation, including fibrinolysis. It measures *in vitro* the kinetics of clot formation and dissolution by a mechanical process that monitors very low shear elasticity changes.

The Thrombelastograph® (TEG®) System, comprised of the TEG® Hemostasis Analyzer and the TEG® Analytical Software, is designed to perform a whole blood coagulation test that produces a hemostasis profile. The TEG® Hemostasis Analyzer automatically records the viscoelastic changes in a sample of whole blood, plasma or platelet-rich plasma as the sample clots, retracts and/or lyses. The resultant profile is a measure of the kinetics of clot formation and dissolution of clot quality (the ability to perform the work of coagulation). Because the TEG® system monitors shear elasticity (a physical property), it is sensitive to all the interacting cellular and plasmatic components in the blood that may affect the rate or structure of a clotting sample and its breakdown. The overall profile can be qualitatively or quantitatively interpreted in terms of the hypo, normal or hypercoagulable state of the sample, the degree of lysis, and other measurements of coagulopathy.

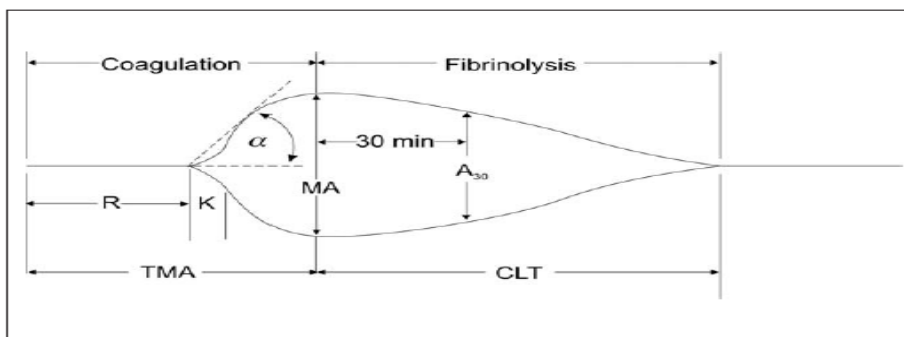


Figure 1.2. TEG® tracing parameters

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

- R:** The time from when the sample is put into the TEG® Analyzer until the first sign of clot formation (amplitude of 2 mm) is reached.
- K:** The time from the R, or beginning of clot formation, to a fixed level of clot firmness (amplitude of 20 mm) is reached.
- Angle (α):** The rate of clot growth.

- ❑ **MA** (Maximum Amplitude): Maximum strength or stiffness (maximum shear modulus) of the developed clot. MA measures the strength of the clot.
- ❑ **CI**: These four main clotting parameters are also combined to yield an index of coagulability (CI) that describes the patient's overall coagulation.

### Specimen Requirements

#### 1. **Venipuncture- whole blood:**

- a. Draw specimen into a plastic syringe without any anticoagulants using a 19G needle.
- b. Discard the first 2-3 ml, which contains tissue or line contaminants (can be used for other non-coagulation testing).

**TEG® test results may be adversely affected by such factors as tissue fluids or contamination from catheter lines.**

- c. Attach a clean plastic syringe and gently draw 1-3 ml of blood.

**The optimum time, from the time the blood enters the syringe to the time it is placed in the TEG® instrument, is 4 minutes.**

- d. The patient label on the specimen should also indicate the specimen type (i.e., baseline, 10 min. post-protamine, etc.) and time collected.

#### 2. **Indwelling venous blood line:**

**Do not obtain blood from a heparinized access line, lock, or indwelling heparin lock**

- a. Discontinue fluids drip, if required.
- b. Draw 10 cc of blood with one syringe—discard.

**TEG® test results may be adversely affected by such factors as tissue fluids or contamination from catheter lines.**

- c. Attach a clean plastic syringe and gently draw 4.5 ml of blood.

**The optimum time, from the time the blood enters the syringe to the time it is placed in the TEG® instrument, is 4 minutes.**

- a. The patient label on the specimen should also indicate the specimen type (i.e., baseline, 10 min. post-protamine, etc.) and time collected.

#### 3. **Citrated whole Blood:**

- a. Draw specimen into a plastic syringe without any anticoagulants using a 19G needle.

- b. Discard the first 2-3 ml, which contains tissue or line contaminants (can be used for other non-coagulation testing).
- c. Using a new syringe, draw 4.5mL of blood and transfer to a blue-caped sodium citrated tube.
- d. Mix sample 3-5 times to mix (don't mix again until ready to assay).

**When using Sodium Citrated samples, TEG testing must wait 15 minutes prior to analysis to allow equilibration of sample within anticoagulant. Do not test samples greater than 2 hours old.**

### Interfering Substances

1. Traumatic sampling of blood will reflect the trauma of the phlebotomy and not coagulation of the patient.
2. The TEG® test may be affected by hemodilution, cardioplegia solutions, hypothermia, platelet dysfunction, hypofibrinogenemia, other coagulopathies, and certain medications.
3. Delay of greater than 4 minutes from time of blood draw to TEG testing could cause invalid results.

### Reference Range

Analyte	0-18 yrs	18-150 yrs
R (Minutes)	5-10	4-9
K (Minutes)	1-3	1-3
Alpha (Degrees)	52-67	59-74
MA (mm)	55-74	55-74

### Critical/Alert Values

None

### Quality Control

Two levels of liquid controls are required each day of patient testing. Perform the daily maintenance prior to testing controls.

### **QC Preparation:**

1. Remove control materials from refrigerator and allow them to reach room temperature (10-15 minutes).
2. Reconstitute lyophilized control according to manufacturer's instructions and allow 10 minutes for adequate rehydration, shaking at reconstitution and again after five minutes.
3. Once reconstituted, the controls are stable for 2 hours.

### **Baseline Testing:**

1. Perform a baseline test by following the prompts displayed on the computer.

2. For a given channel, select the channel, then click on Baseline. Move the lever to the Load position. Wait until the message “Baseline is OK” is issued.
3. If the baseline is “off center”, turn the screw on the back of the instrument labeled BASE for that channel. Continue to repeat the test and make adjustments until the values under “Min” and “Max” are between 1800 and 2200.
4. Hit DONE to go back to the main screen.

**Control Analysis:**

1. The following fields identify the controls in the database:

**Sample Type:** Select the correct level of biological control.

**Patient ID:** Type in lot number of the control located at the bottom of the vial.

**Operator ID:** Enter your operator ID. Click on the “Main” button to return to the TEG® screen.

2. Enter the above information for each channel to be tested.
3. After the above data has been inputted, click on the first channel that will be tested so it turns blue.
4. Load the clear disposable cups and pins for each TEG® column.

Loading cups and pins

- a. With the lever in the load position, slide the white carrier half way down the platform.
- b. Pick up a disposable cup and pin from the Styrofoam tray. (Do not touch the outside of the pin or the inside of the cup.) Place in the cup well.
- c. 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.
- d. When the top of the white carrier is flush with the bottom of the column, push the pin firmly into place using the plastic pusher located at the bottom of the white carrier. Counterbalance the analyzer by holding your hand on top while pushing the pin.
- e. Make sure that the pin is correctly loaded by checking that the bottom tip of the skewer is touching the inside bottom of the disposable pin.

- f. Slide the white carrier halfway back down and push the cup firmly into the cup well. The cup should rest flush with the white carrier and should not pop up.

QC testing:

1. Pipette 20 µl of .2M calcium chloride (included in the biological control kit) into each TEG® well.
2. Pipette 340 µl of reconstituted control into the well of each channel.
3. Raise the column and move the lever to test in the first channel.
4. Quickly press F10 on the keyboard to activate the first sample
5. Repeat steps 3 and 4 for other testing columns.
6. Terminate control after MA is achieved to expedite matters. Print the tracings by pressing the F6 key, check the printed output with the ranges established by the Laboratory Quality Assurance, sign it and keep the printed output in a file.
7. Record the results on the TEG® laboratory QC log in the column for the appropriate control level, date, and initial.
8. Repeat with level 2.

Failure to obtain the expected value for four out of four parameters for level 1 (3 out of 4 parameters for level 2 only) (R, K, alpha, and MA) may be an indication of product deterioration, TEG® instrument or procedural problems. Check the temperature. If the temperature appears correct, re-try using fresh vial of the control and fresh calcium chloride. If the results are still abnormal, contact technical support (1-800-438-2834).

Document any out of range quality control corrective action on the log provided.

Record all the data in the troubleshooting log.

**DO NOT REPORT PATIENT RESULTS IF THE QC IS OUTSIDE ACCEPTABLE LIMITS.**

### Specimen Types

1. **Baseline before procedure:** 1 TEG® sample in a blue heparinase cup. Heparinase is required. Or the use of a plain cup if the patient is not on heparin.
2. **Post-protamine:** Two measuring columns run simultaneously are necessary: (It is possible another sample may be sent after another dose of protamine is given and before patient is discharged to ICU.) This sample should also be placed in a

blue cup and pin.

The patient sample should be split between a blue heparinase cup on one channel and a clean cup on another channel.

### Patient Test Procedure (Whole Blood):

#### Starting the run

To enter sample data for a citrated whole blood sample, input the information into the TEG® screen of the TEG® program.

Move the cursor to the channel you choose to run and enter the following data by using the pull-down menus. Press 'Enter' key or click in another box to continue.

**Sample Type:** This presents a pop-up box selecting pre-defined types. Select the appropriate sample type (i.e. citrated Kaloin).

**Patient Name:** Type in the 'Medical Record number' of the patient. Press 'Enter' key.

**Last Name:** Type in the 'last name' of the patient. Press 'Enter' key.

Identify the specimen type:

1. Baseline or
2. Post-protamine

If a bleeding problem is evident and other samples are drawn, identify the sample further. (e.g., 'postop/25mg protamine').

**Operator ID:** Main program screen.

Note: If data is not identified before you print the tracing, the normals will not appear on the report.

To enter sample data for a whole blood sample, input the information into the TEG® screen of the program.

Move the cursor to the channel you choose to run and enter the following data by using the pull down menus. Press 'Enter' key or click in another box to continue.

1. Load the cups and pins (see 'Loading Cups and Pins- Page 4).
2. Add 1 cc of whole blood to the vial containing kaolin; cap and mix gently by inversion five times.

3. Pipette 360µl of the mixture into the first pre-warmed disposable TEG® cup.  
**3a. If using Sodium citrated sample pipette 20µL of 0.2M CaCl<sub>2</sub> into each cup and 340µL of patient sample instead.**
4. Pipette another 360µl into the second channel, if desired.  
**4a. If using Sodium citrated sample pipette 20µL of 0.2M CaCl<sub>2</sub> into each cup and 340µL of patient sample instead.**
5. While the lever is still in the Load position, raise the white carrier up carefully until it is flush with the bottom of the column. Repeat for the second channel, if desired.
6. Move the lever to the right (Test position), resting your hand on top of the analyzer to prevent tipping. Repeat for the second channel, if desired.
7. Press [F10] on the computer keyboard or click on the green Start icon to begin the test. Repeat for the second channel, if desired.

If you have followed the sample loading procedure correctly, the sample information display for that channel number changes from white to yellow. Channels that are color-coded yellow are inactive channels (even if an inactive channel is selected, turning it blue, the channel number region will remain either yellow for inactive or green for active in this screen).

Once you have started one or more blood samples on the TEG® Analyzer, you can view their progress by selecting a channel and then clicking the “Max” button.

If the channel does not activate, call our service representative (1-800-438-2834).

After the test has run for 30 minutes the physician may request the pending results be printed for review. Note that any results still in asterisks are not finalized.

Final results should be printed and given to the clinician responsible for interpretation. After interpretation has been noted, results are then placed on the patient’s chart.

#### Ending the run

1. If the software has not already terminated the test, end the test on the computer.
2. In the Main screen or TEG® screen, select the channel and click on the red Stop icon or press F11 to end the sample.

**If you have followed the channel terminating procedure correctly, the sample information display for that channel number changes from green. This also helps**

**distinguish between active and terminated (or “completed”) channels on the “Main” screen.**

3. Slide the lever to the left to the “Load” position and then press down on the lever to eject the pin.
4. Slide the white carrier down to the platform. Be sure the pin has dropped into the cup.
5. Press the white carrier down firmly against the platform. This will release the cup from the white carrier.

### Calculations

None

### Results Reporting

1. Report all test results to ordering physician or authorized person in a timely manner. Recheck abnormal values and report **IMMEDIATELY**.
2. Results are scanned into the Electronic Medical Record.

### Reagents

1. **Disposable Cups and Pins for the 5000 series:** Store them at room temperature (15-30°C) in the Styrofoam tray and keep covered when not in use.
2. **Disposable Heparinase I Cups and Pins for the 5000 series, 2IU:** The blue (heparinase) cups and pins are stored at 2 -8°C until use.
3. **Kaolin, Premeasured:** The Kaolin vials are stored, until the expiration date, at 2 - 8°C until use.
4. **0.2M CaCl<sub>2</sub>:** Store at 2-8°C. Stable until expiration date.
5. **TEG® Biological Controls - Level I and II:** Store at 2 -8°C. Unopened vials stable to expiration date. Reconstituted vials are stable for 2 hours at room temperature.

### References

1. Haemoscope Thrombelastograph® Coagulation Analyzer User Manual, 1999.