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|  TEG Thromboelastograph Using the TEG 5000 Analyzer |
| **Purpose** | The TEG system is a non-invasive diagnostic instrument designed to monitor and analyze thehemostasis state of a blood sample in order to assist in the assessment of patient clinicalhemostasis conditions. The TEG system is indicated for use with patients where an evaluationof their blood hemostasis properties is desired. Hemostasis evaluations are commonly usedto assess clinical conditions such as post-operative hemorrhage and/or thrombosis during andfollowing cardiovascular surgery, organ transplantation, trauma, and cardiology procedures. |
| **Policy Statements** | This procedure applies to all clinical laboratory scientists performing coagulation tests, section supervisor and section pathologist. |
| **Principle and Clinical Significance** | The TEG 5000 analyzer records the kinetic changes in a sample of whole blood as the sample clots, retracts and/or lyses (breaks apart). The TEG 5000 analyzer gives a hemostasis profile of the time it takes for the first measurable clot to be formed, the kinetics of clot formation, the strength of the clot and the breakdown of the clot or fibrinolysis; *TEG analyzer exterior front components*1.) Carrier2.) Cupwell (x2)3.) Carrier Ribbon Cable (x2)4.) Column5.) Lever in Load position6.) Power switch7.) Temperature controller8.) Front Cover9.) Motor indicator10.) Lever in Test position11.) Carrier shafts12.) Platform13.) Front leveling foot (x2)*TEG tracing parameters***Primary Clot formation and lysis parameters;**1. **R or R-time (Reaction Time)**

The time from the start of a sample run until the first significant levels of detectable clot formation (amplitude = 2 mm in the TEG tracing). This most represents the enzymatic portion of coagulation. This is the point at which most traditional coagulation assays reach their endpoints. R-time is prolonged by anticoagulants and factor deficiencies and is shortened by hypercoagulable conditions. |
|  | 1. **K or K-time**

 Achievement of a certain clot strength. K is a measure of the time from R until a fixed level of clot strength is reached (amplitude = 20 mm). This most represents initial clot kinetics. K is shortened by increased fibrinogen level and, to a lesser extent, by increased platelet function, and is prolonged by anticoagulants that affect both. If the amplitude does not reach 20 mm, K is undefined. ***Caution:*** *If the MA of the sample is less than 25 mm, do not use K for clinical decisions. In*  *these decisions. In these samples, use angle.* 1. **Angle (**α**)**

 Angle or α measures the rapidity of fibrin build-up and cross-linking (clot strengthening). This most represents fibrinogen level. Angle relates to K, since both are a function of the rate of clot formation. Angle is more comprehensive than K, since there are hypocoagulable conditions in which the final level of clot strength does not reach an amplitude of 20 mm (in which case K is undefined). Similar to K, Angle is made larger by increased fibrinogen levels and, to a lesser extent, by increased platelet function, and is decreased by anticoagulants that affect both. 1. **MA**

 MA, or Maximum Amplitude, is a direct function of the maximum clot strength. In tests where platelets are part of the clot, this parameter most reflects platelet function / aggregation. Clot strength is the result of two components - the modest contribution of fibrin and the much more significant contribution of the platelets. Approximately 80% of the contribution to MA is from platelets, and the remaining 20% from fibrin. This remaining 20% is the only component measured by the traditional PT and aPTT.1. **LY30**

 Percent lysis 30 minutes after MA is reached. The LY30 measurement is based on the reduction of the tracing area that occurs between the time that MA is measured until 30 minutes after the MA is defined.Secondary Clot formation and lysis parameters;1. **G**

 Shear elastic modulus strength (SEMS). The MA parameter can be transformed into the actual measure of clot strength (G) using the formula below, and is measured in dyn/cm2 divided by 1000 (displayed in the software as Kd/sc). The absolute SEMS of the sample can be calculated from MA as follows: *G = (5000MA/(100-MA))/1000* An amplitude of 50 mm corresponds to a SEMS of 5000 dyn/cm2. An increase in MA from 50 mm to 67 mm is equivalent to a two-fold increase in the SEMS. The G parameter not only provides a measurement of clot firmness in force units, but also is more indicative of small changes in the clot strength or clot breakdown than is the amplitude in mm because it is an exponential reflection of MA. |
| **Test Codes****Materials** | TEG1, TEGH, RTEG1, RTEGH |  |  |  |
|  | **Reagents** | **Supplies** | **Equipment** |  |
|  | • Item 6300 Kaolin (25vials/box)• Item 07-034 Functional Fibrinogen vials (15vials/box)• Item 7003 Calcium Chloride 0.2M (5cc vial)• Item 8001 Level I Control (12 vials /box)• Item 8002 Level II Control (12 vials/box)● Item 07-032 Rapid TEG Reagent (14vials/box) | • Item 6211 Plain Cups and Pins (20ea/box)• Item 6212 Heparinase Cups and Pins (20ea/box)• Item 01-009 Pipette Tips, RT-20 (100/box)• Item 01-08 Pipette Tips RT-200 (100/box) | • Item 07-022 Thromboelastograph Hemostasis Analyzer, Model 5000 |  |
| **Sample** | To collect a citrated blood sample (2.7cc or 1.8cc Blue top tube):Determine the appropriate site for blood collection and draw a discardTube (3mL in a red top tube):a.**Venipuncture:** Discard the first 3 mL.b. **Central venous or pulmonary artery catheters:** Draw from theappropriate port and discard the first 3 mL.c. **Arterial lines:** Discard the first 3 mL.2. Draw one sodium citrate tube of blood to the appropriate level.3. Gently invert the tube 5 times to mix.4. Place the tube horizontally on the table until it is time to analyze theblood. Wait 10 minutes before running sample. Unacceptable samples include:1. Clotted samples
2. Centrifuged samples
3. Samples collected in gel tubes
4. Samples not tested within 2 hours of collection
5. Under-filled tubes
6. Samples should not be sent through the pneumatic tube system
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| **Special Safety** **Precautions****Daily Start up****Daily Maintenance Checks** | The storage and handling of Haemonetics® reagents (e.g., Kaolin,PlateletMapping® Assay, etc.) and Level I and II quality control samples differdepending on the type of reagent or control. Refer to each product insert forstorage and handling instructions.Turn the TEG instruments on by pressing the green power switch on both analyzers. If using only one instrument, instrument #1 must be used. Instrument #2 cannot be used without instrument #1 being turned on. Allow the temperature for both instruments and all four columns to reach 37°C. Double click on the TEG icon. Select the ▼ for User name and select “Site Administrator” then type in “teg” as the Password. On the next screen click on Temporary Operator and select “logon”. To ensure the proper test performance, test results reporting, and electronicfunctioning of the TEG analyzer, the following daily maintenance checks mustbe conducted. ( Refer to Operation Overview section 7-5 pages 97-101 TEG 5000 Users Manual)Level the analyzerCheck the carrier ribbon cables (applies to carriers that do not include ametal retaining plate at the back)Verify that the temperature controller display is lit and that the temperaturereadout for each column is correctPerform an eTestAs a reminder to complete the daily maintenance checks, the following promptdisplays when you first enter the TEG screen in the TEG Analytical Software (TAS): If any of the maintenance checks reveal a problem with the analyzer, contactTEG System Technical Support for assistance (phone number is taped to each analyzer).Clean the surfaces of the analyzer as needed, but no less than weekly, **do not use bleach as it is corrosive to analyzer components.**Using disinfectant wipes or 70% isopropyl alcohol, thoroughly clean the following components:  ● Outer surfaces of the analyzer ● Platform (remove first) ● Surfaces behind carriers and above columns. ● Outer surface of columns and column levers.  Use an alcohol swab to disinfect the cupwell and carrier surfaces.The lower column and skewer tip should be cleaned as needed; 1. Fill a disposable cup with alcohol and place in the cupwell. 2. Cut a 2x2 gauze pad in quarter sections. 3. Ensure the lever is in ***Load*** position.***Caution:*** *Do not clean the skewer with the lever in Test* *position as this can**damage the thin torsion wire attached to the skewer.* 4. Wrap an alcohol soaked gauze section around the tip of the skewer. 5. Gently move the carrier to the raised position to hold the gauze in contact with the skewer. 6. After 10 minutes of contact, lower the carrier and remove the gauze. 7. Using an alcohol swab, clean the interior of the column, removing any residue.  |
| **Quality Control** | Level I and Level II quality control samples must be run on **each** channel on theTEG analyzer. Controls should be run every 8 hours with testing. For each TEG analyzer that you are testing, you need to prepare one vial of Level I control and one vial of Level II control.The following outlines the order in which control samples should be prepared and run on each analyzer;Prepare 1 vial of Level I control material (enough for two samples) by adding the distilled water included in the kit. Mix vigorously for 30 seconds and insure that all of the lyophilized powder is being dissolved. Let sit upside down for 5 minutes in order to dissolve any residual powder in the cap. Mix vigorously for 30 seconds then stand right side up for an additional 5 minutes.Load cups and pins ( Section 7-14 through 7-16 pages 106-108 TEG 5000 Users Manual)Simultaneously run the Level I samples on each channel of the analyzer ( Section 7-10 pages 102-105 ).TEG 5000 Users Manual). Ten minutes after the Level I tests have started, prepare 1 vial of Level IIcontrol material follow the same instructions as above.When the MA has finished being defined (the asterisk next to the value nolonger appears) for the Level I samples, terminate the samples.Verify control sample results.***Caution:*** *After the control material has been reconstituted, the samples must**be run within 2 hours.* |
| **Procedure** | **Step** | Action | **Related Document** |
|  | 1 | In the *TEG* screen, complete the *Patient name* (name and MR number)field for the appropriatechannel:  **If this is… Then do the following…**A *new* patienta. Click to display the Select case modescreen.b. Select the *Add case* option and click **Done**.c. Complete the *Create case* screen.d. Click **Done**.e. In the *Patient name* field that correspondsto the channel, click the down arrow andselect the patient name.An *existing* patient a. In the *Patient name* field that correspondsto the channel, click the down arrow andselect the patient name. |  |
|  |  2 | In the *ST* (sample type) field that corresponds to the channel, select the sample type you want to run from the drop-down list.For example, to run a Citrated Kaolin sample, you would select “CK”,(Citrated Kaolin) or “CKH”, (Citrated Kaolin with Heparinase).To run Rapid TEG, you would select “CRT” (Citrated Rapid TEG), or CRTH (Citrated Rapid TEG with Heparinase). |  |
|  |  3 | Load the cups and pins for all the channels that you are going to run.  | “Loading the cups and pins” Section 7-14. |
|  |  4 | TEG1, HTEGH;1. Pipette 20ul of CaCl**2** into the cup.
2. Transfer 1ml of well mixed citrated blood into a kaolin vial. Invert gently 4 times.
3. Immediately add 340ul of the kaolin treated sample into the cup.
4. Slide the carrier up gently so that it is flush with the column.

RTEG1, RTEGH; a.) Pipette 20ul of distilled water into the vial. b.) Replace stopper and swirl the vial to mix. Do not  invert or shake. c.) Allow it to stand for 5 minutes at room temperature. d.) Refrigerate when not in use. Store at 2°C - 8°C. e.) Pipette 10ul of reconstituted Rapid TEG reagent into the cup.  f.) Pipette 20ul of CaCl**2** into the cup. g.) Immediately add 340ul of well mixed citrated blood into the sample cup and pipette up and down 3 times to mix (avoid bubbles). h.) Slide the carrier up gently so that it is flush with the column. i.) Rapid TEG should not be used when Platelet  Mapping is being performed.Rapid TEG shortens the clotting time by adding tissue factor to the reaction. This will be noted by the markedly decreased R value.***Caution:*** *Do not raise the carriers too quickly. If a carrier is pushed up too quickly, the pin displaces the sample with enough force to splash material onto the flange of the cup. This can affect test results.* |  |
|  | 5 | Move the lever to **TEST**.From the *TEG* screen, highlight the corresponding channel and click “GO” (F10).The channel in the *TEG* screen turns green, indicating it is active. The **Active** button flashes at the bottom of the screen when the sample is selected. |  |
|  | 6 | Repeat steps 4 - 5 for each channel on which you are running the test.Click **Done** to return to the *TAS Main* screen |  |
|  | 7 | You can manually terminate the sample earlier if you require only some parameters to be finalized. In TAS, a parameter is finalized when an asterisk no longer appears next to it on the tracing.To manually end a sample run:1. From the *TAS Main* screen, select the channel that you want to stop.2. Click “Stop” (or press **F11**).A message similar to the following appears:3. Click **Yes** to terminate the sample.The channel turns white, indicating that the sample is terminated.4. Eject the blood sample and properly dispose of it. | See “Ejecting the cups and pins” on page 7-16 |
| **Computer entry,** **QC and patients****In Sunquest** | **Step** | **Prompt** | **Action** |
|  | 1 | Orderable test code: TEG1 (routine TEG) TEGH (TEG Heparinase cup) RTEG1 (rapid TEG) RTEGH (rapid TEG Heparinase cup) TEGP (Platelet Mapping) |  |
|  | 2 | After testing has been completed enter results for QC in Sunquest.Funtion: MEMWorksheet: TEGParameters to result (TEG1 TEGH):RCT,RCTH - R, (clear cup, heparinase cup)KCK, KCKH - K, (clear cup, heparinase cup)ANGL, ANGLH - Angle (clear cup, heparinase cup)1MA, 1MAH - Maximum Amplitude (clear cup, heparinase cup)LY30, LY30H - %Lysis 30 minutes (clear cup, heparinase cup) Parameters to result (TEGP):ADPI - % inhibition with ADP, AAPI - % inhibition with Arachidonic AcidRCT,RCTH - R, (clear cup, heparinase cup)KCK, KCKH - K, (clear cup, heparinase cup)ANGL, ANGLH - Angle (clear cup, heparinase cup)1MA, 1MAH - Maximum Amplitude (clear cup, heparinase cup)LY30, LY30H - %Lysis 30 minutes (clear cup, heparinase cup) Test methods to result: HTEG1 (Instrument 1, channel 1) HTEG2 (Instrument 1, channel 2), HTEG3 (Instrument 2, channel 1), HTEG4 (Instrument 2, channel 2).QC Codes:TL1 - TEG Level 1TL2 – TEG Level 2 | Example of QC Level 1 entry:MANUAL RESULT ENTRYWORKSHEET: TEG DEVICE LAB LOCATION: R MIN MINNEAPOLIS TEST-1: RCT RTEST-2: KCK KTEST-3: ANGL ANGLETEST-4: 1MA MATEST-5:  CAP METHODS TO BE USED DURING THIS RESULT ENTRY SESSION TEST - METH TEST - METH TEST - METH TEST - METH TEST - METH RCT KCK ANGL 1MA ACCEPT (A) OR MODIFY (M) ? M RCT : HTEG1 HAEMONETICS TEG 1KCK : HTEG1 HAEMONETICS TEG 1ANGL : HTEG1 HAEMONETICS TEG 11MA : HTEG1 HAEMONETICS TEG 1  CAP METHODS TO BE USED DURING THIS RESULT ENTRY SESSION TEST - METH TEST - METH TEST - METH TEST - METH TEST - METH RCT HTEG1 KCK HTEG1 ANGL HTEG1 1MA HTEG1 ACCEPT (A) OR MODIFY (M) ? A WORKLOAD DATA ENTRY WORKLOAD DATA FOR: MANUAL RESULT ENTRY ACC. NO.: C-TL1 TEG LEVEL 1 LOT NUMBER: 1101-1201 RCT : 2.1 0.80 STANDARD DEV FROM MEANKCK : 0.8 -0.40 STANDARD DEV FROM MEANANGL : 81.4 -0.53 STANDARD DEV FROM MEAN1MA : 53.8 0.31 STANDARD DEV FROM MEAN ACCEPT (A), MODIFY (M), OR REJECT (R) ? A |
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| **Result Reporting** | Patient results are reported in Sunquest just as the QC values. Print reports that include the tracings on the color printer. These reports will be scanned to Power Chart the next day. **In order to print a report**; highlight the appropriate tracings (select the “Multi” key and then “Superimpose” the tracings if necessary). Select report, Continue, Print. Place a large Sunquest label on the report to be scanned. After reports have been scanned they will be kept in a notebook at the bench.**If it is necessary to e-mail a copy of a tracing to a provider**; highlight the appropriate tracings (select the “Multi” key and then “Superimpose” the tracings if necessary). Select report, Continue, Print, Adobe PDF, Type in Patient name and MR number, file, send file, continue, type in your CE number and Password, e-mail to recipient (Subject “Secure :”), Save to send.**If it is necessary to scan a TEG report into power chart (from the scanner in the lab reception area);** log into Powerchart, select MRN in drop down box of search area, enter patients MRN and enter, select appropriate episode, click on “Menu” along left side, click on “Clinical Documents”, right click on gray date bar, change criteria, in the “From” area go back 4 months, click on “O.K.”, select “Lab Documents”, click on scan icon at top (second icon under clinical documents), click on drop down under type, select “Coag Reports”, select correct date and time using information on the lab barcode label, enter “CHILDRENS” in subject area, click on “scan”, select 256 color under image mode, place report in scanner upside down with print away from you, click “scan”, close, sign.   |
| **References** | TEG 5000 User Manual – Haemonetics Corporation, Haemoscope Division 6231 Howard Street, Niles Illinois, 60714 USA[TEG 5000 Users Manual](http://khan.childrensmn.org/Manuals/Lab/SOP/Coag/Res/208267.pdf)Thrombosis Journal – Evaluation of TEG platelet mapping assay in blood donorsThrombosis Research (2005) 117, 49-53 Effects of Dietary supplements on coagulation and platelet functionDrugs that affect platelet function – Rudiger E. Scharf PhD, FAHATEG Hemostasis System Rapid TEG Reagent Instructions for Use. Haemonetics Corporation, Haemoscope Division 6231 Howard Street, Niles Illinois, 60714 USA[www.haemonetics.com](http://www.haemonetics.com) 06-430 (AC) 2012-06 |
| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Al Quigley | 06/25/14 | Initial Version |
| 2 | Al Quigley | 12/11/18 | Added instructions for Rapid TEG application |
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