Beaumont Laboratory
Royal Oak

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TEG Approved Physicians

TEG®6s Procedure
Citrated: K, KH, RT, FF
Citrated: K, RT, FF (Lysis Cartridge)
Royal Oak STAT Lab

RC.CH.CSL.TEG.PR.001r03 for PolicyStat

Principle

The TEG® 6s Hemostasis System consists of the TEG 6s Hemostasis Analyzer and approved multichannel TEG Cartridges. The TEG 6s Hemostasis System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a venous blood sample. The TEG 6s Hemostasis System records the kinetic changes in a sample of 3.2% citrated whole blood as the sample clots.

The **Citrated: K, KH, RT, FF Cartridge** tests hemostasis using four different assays/reagents simultaneously, one in each of the four cartridge channels:

CK (Citrated Kaolin) Principle: Kaolin is a standardized reagent consisting of dry Kaolin and 0.85% Saline solution. Use of these particles of hydrated aluminum silicate shortens coagulation time because Kaolin acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with $CaCl_2$ to neutralize any sodium citrate in the blood. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

CRT (Citrated RapidTEG®) Principle: RapidTEG® maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of Kaolin and Tissue Factor (TF). This closely reflects the physiological clotting process and yields results significantly faster than a native, Kaolin, and/or TF activated test. $CaCl_2$ is included to neutralize any sodium citrate in the blood. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

CKH Principle: Heparin is commonly used as an anticoagulant in surgical procedures and can mask developing coagulopathies. The Kaolin with Heparinase assay will rapidly and specifically neutralize the anticoagulant property of Heparin. $CaCl_2$ is included to neutralize any sodium citrate in the blood. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

CFF Principle: The Functional Fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor (ReoPro®) that binds to GPIIb/IIIa receptors. The Functional Fibrinogen reagent fully inhibits all the platelets, thereby excluding their contribution to clot strength (MA), and therefore measures only the functional fibrinogen contribution to clot strength. Functional Fibrinogen is combined with $CaCl_2$ to neutralize any sodium citrate in the blood. Clotting characteristics are described by

the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

The **Citrated: K, RT, FF Cartridge (Lysis Cartridge)** contains three independent assays (CK, CRT, and CFF) and the system output consists of a table of numerical values for parameters CK-R, CK-LY30, CRT-MA, and CFF-MA.

CK Principle: Kaolin is a standardized reagent consisting of dry Kaolin and saline solution. Kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample. Use of these particles of hydrated aluminum silicate shortens coagulation time because Kaolin acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with CaCl2 to neutralize any sodium citrate in the blood. Clotting characteristics are described by the functional parameters R (clotting time) and LY30 (fibrinolysis after 30 minutes of reaching maximum clot strength).

CRT Principle: RapidTEG maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of Kaolin and Tissue Factor (TF). This closely reflects the physiological clotting process and yields results significantly faster than a native, Kaolin, and/or TF activated test. CaCl2 is included to neutralize any sodium citrate in the blood. Clotting characteristics are described by the functional parameter MA (maximum clot strength).

CFF Principle: The Functional Fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor that binds to GPIIb/IIIa receptors. By excluding the platelet aggregation contribution to clot strength (MA), the reagent measures fibrinogen contribution. Functional Fibrinogen is combined with CaCl2 to neutralize any sodium citrate in the blood. Determining the independent contribution of platelets and fibrinogen further improves the use of the TEG 6s System in helping to detect and diagnose hemostasis defects. Clotting characteristics are described by the functional parameter MA (maximum clot strength).

Clinical Significance

The TEG® 6s Hemostasis System is intended for in vitro diagnostic use to provide semiquantitative indications of the hemostasis state of a venous blood sample (3.2% citrated whole blood) using the Citrated Multichannel Cartridges described above.

Results from the TEG® 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for TEG® 6s System use is with adult patients where an evaluation of their blood hemostasis properties is desired. The **Citrated: K, KH, RT, FF Cartridge** is used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during, and following the procedure. The **Citrated: K, RT, FF Cartridge (Lysis Cartridge)** is used to assess clinical conditions in a trauma setting to assess hemorrhage or thrombosis conditions.

Specimen Collection and Handling

For blood draws, draw a discard tube first. Use only 3.2% sodium citrate tubes, completely filled. No other tube type is acceptable. After collection, gently invert the tube 5 times. **Samples may not be sent through the pneumatic tube system.** Minimum 15 minutes of incubation at room temperature is required prior to testing. Samples must be tested within 2 hours of draw.

Caution: Never check for clots using wooden applicator sticks.

Testing is performed on well-mixed whole blood. Before adding sample to the cartridge, gently mix the citrate tube 5-7 times.

Equipment and Reagents

TEG® 6s analyzer
Transfer pipettes
Citrated: K, KH, RT, FF cartridges sealed with dessicant in foil pouch. Cartridges must be refrigerated (2°C to 8°C) in sealed foil pouches when not in use. Each cartridge contains the following reagents for the indicated channel:

CK (Citrated Kaolin): Kaolin (concentration 0.004% w/w) + $CaCl_2$ (0.9 M)
CRT (Citrated RapidTEG®): Dried Kaolin (concentration 2% w/w) + Tissue Factor (concentration 2 mcg/mL) + Calcium Chloride (0.8 M)
CKH (Citrated Kaolin with Heparinase): Kaolin (concentration 0.007% w/w) + $CaCl_2$ (0.9 M) + Heparinase (concentration ≥ 400 IU/mL, adequate to reverse 5 IU heparin/mL in blood).
CFF (Citrated Functional Fibrinogen): Tissue Factor (concentration 0.3 mcg/mL) + $CaCl_2$ (0.8 M) + Abciximab (concentration 2 mg/mL).

Citrated: K, RT, FF cartridges, each sealed with a desiccant pack in a foil pouch. Cartridges must be refrigerated (2°C to 8°C) in sealed foil pouches when not in use. Each cartridge contains the following dried reagents for the indicated channel:

CK (Citrated Kaolin): Kaolin (concentration 0.004% w/w) + Calcium Chloride (0.9 M)
CRT (Citrated RapidTEG) Kaolin (concentration 2% w/w) + Tissue Factor (concentration 2 mcg/mL) + Calcium Chloride (0.8 M)
CFF (Citrated Functional Fibrinogen): Tissue Factor (concentration 0.3 mcg/mL) + Calcium Chloride (0.8 M) + Abciximab (concentration 2 mg/mL)

Calibration

Routine calibration not required.

Quality Control (see also, Individualized Quality Control Plan for TEG®6s)

Internal Controls

The Power-On Self-Test performs internal QC checks on all analyzer functions prior to cartridge insertion. The analyzer also performs internal QC checks during a pretest when the cartridge is inserted. This verifies that all electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. When in use, the analyzer monitors critical operational parameters throughout the test. Failure of any internal QC will invalidate the test and an error message will display.

External Controls

External liquid QC must be performed with each new shipment and new lot of multichannel cartridges, and at least monthly. Two levels of external liquid QC must be tested for each cartridge type and each analyzer.
Level 1 Normal QC: Fresh healthy adult donor citrated whole blood. The donor must meet Haemonetics donor requirements, including taking no medications known to affect coagulation

Level 2 Abnormal QC for Citrated: K, KH, RT, FF cartridge
Haemonetics Abnormal QC (REF 07-662-US):

1. Allow one control vial and one diluent water vial to warm to room temperature for 10 min.
2. Making sure the lyophilized material is on the bottom of the control vial; remove the seal and the stopper.
3. Slowly pour contents of the diluent water into the control vial. If any water drips out, start over.
4. Re-insert the stopper and shake vigorously until fully reconstituted. Let stand for 5 minutes.
5. Shake again vigorously and let stand 5 more minutes.

Level 2 Abnormal QC for Citrated: K, RT, FF cartridges (Lysis)
Haemonetics Abnormal & Lysis QC (REF 07-663-US)
Two lysis cartridges will be used for two separate Level 2 controls:

Abnormal Control

1. Allow one Abnormal control vial and one diluent water vial to sit for approximately 10 minutes to equilibrate to room temperature.
2. Make sure the lyophilized material is on the bottom of the Abnormal control vial. You may need to tap the vial a few times. Remove the seal and stopper of the Abnormal control vial, taking care to avoid sharp metal edges.
3. Slowly pour the contents of the diluent water vial into the Abnormal control vial. Make sure no water drips out. If any water drips out, start over.
4. Re-insert the stopper into the Abnormal control vial. Hold the stopper in place, vigorously shake the Abnormal control vial until fully reconstituted. Let it stand for 5 minutes at room temperature.
5. Shake the Abnormal control vial vigorously again and let stand 5 more minutes. Repeat until there is no undissolved material remaining in the vial.

Lysis Control

1. Allow one Abnormal control vial, one Lysis control vial, and one diluent water vial to sit for approximately 10 minutes to equilibrate to room temperature.
2. Make sure the lyophilized material is on the bottom of the Abnormal and Lysis control vials. You may need to tap the vial a few times. Remove the seal and stopper of the Abnormal control vial, taking care to avoid sharp metal edges.
3. Slowly pour the contents of the diluent water vial into the Abnormal control vial. Make sure no water drips out.
4. Re-insert the stopper into the Abnormal control vial. Hold the stopper in place, vigorously shake the Abnormal control vial until fully reconstituted, and then let it stand for 5 minutes at room temperature.
5. Shake the Abnormal control vial vigorously again and let stand 5 more minutes. Repeat until there is no undissolved material remaining in the vial.
6. Remove the seal and stopper of the Lysis control vial, taking care to avoid sharp metal edges.
7. Remove the stopper of the reconstituted Abnormal control vial.
8. Using a transfer pipette from the Citrated: K, RT, FF cartridge box, transfer the entire contents of the reconstituted Abnormal control vial into the Lysis control vial.
9. Replace the stopper on the Lysis control vial and invert the vial five times to mix the abnormal and lysis material. Repeat until there is no undissolved material remaining in the vial.

Procedure

1. Select the appropriate cartridge from refrigerated storage based on the order:
    a. Viscoelastography (VISLG) = Citrated: K, KH, RT, FF cartridge
    b. Viscoelastography with Fibrinolysis (VISCF) = Citrated: K, RT, FF cartridges (Lysis cartridge)
2. Remove a foil-sealed cartridge from refrigerated storage and allow it to come to room temperature for 5-10 min. Unopened cartridges must be returned to refrigerated storage promptly.
3. Touch the screen on the front of the instrument to illuminate the panel.
4. Enter **Username** (Beaumont User ID / bh number) and **Password** (specific for the TEG®). Username and Password are the same used for TEG Manager.
5. Select "new test" on the screen. (QC is tested by selecting "new qc".)
6. Add a patient by selecting "+" for a new patient. Scan the sample barcode to enter the sample identification number for the patient. Press enter or select "ok".
7. Select the correct sample identification number from the list. Select "next".
8. The message "No patient data available" appears. Select "continue".
9. When prompted, insert the cartridge in the slot on the front of the instrument with the barcode facing to the left.
10. Verify the cartridge with the sample type. (Citrated: K, KH, RT, FF and Citrated: K, RT, FF cartridges both require Blue top NaCitrate.) Select "next".
11. Type patient **Last Name** and **First Name** into the Test Information field and select "next".
12. Ensure that at least 15 minutes has elapsed since collection of the sample.
13. Gently invert the sample 5-7 times to mix. Pipette the sample into the sample well making sure the sample is above the sample indicator arrow and there are no bubbles introduced. Touch "next".
14. IMPORTANT: Physicians will review and interpret the TEG® 6s results in real time over the course of the assay; therefore, it is necessary to **log in to TEG® Manager immediately to enter the MRN as a second identifier**.
    a. Click on the TEG icon at a STAT lab desktop workstation and enter the same username and password used for the TEG® 6s analyzer.
    b. On the Search screen, select "today", then "search". Select the appropriate sample identification number.
    c. Select Patient Name in the lower left corner of the tracing. Enter the patient's MRN into the Accession ID field in duplicate, and select "Done".
15. Results in progress may be viewed on the TEG®6s and in TEG® Manager.
    a. At the TEG®6s the numeric results appear on the screen as they are completed. The results can be reviewed graphically by touching "tracings" in the bottom right corner.
    b. In TEG® Manager, select "search" then select "today" and "search". Most recent results are displayed first.
16. Depending on clotting time, the assay is completed in 25-40 minutes (VISLG) or 50-60 minutes (VISCF). The cartridge slot LED will flash, and user is prompted to remove the cartridge when testing is completed.

Reporting

1. If no instrument errors occur and results are ready to report, **PRELIM verify** in the LIS with the standard comment to indicate that the run is complete. Page the ordering physician.
2. The STAT Lab lead technologist or designee will upload pdf reports daily (Monday-Friday dayshift) to the LIS for reporting in the EMR.

Analytical Measuring Ranges (AMR)

Citrated: K, KH, RT, FF cartridge

CK-R (min)	CK-K (min)	CK-A (degrees)	CK-MA (mm)	CRT-MA (mm)	CKH-R (min)	CFF-MA (mm)	CFF-Fib (mg/dL)
0.4-17	0.5-5	39-83	40-75	40-75	0.3-17	4-52	130-950

Citrated: K, RT, FF cartridge (Lysis cartridge)

CK-R (min)	CK-LY30 (%)	CRT-MA (mm)	CFF-MA (mm)
0.4-17	0.0-22.0	40-75	4-52

No sample dilutions approved, so these are the reportable ranges.

Reference Ranges

Citrated: K, KH, RT, FF cartridge

CK-R (min)	CK-K (min)	CK-A (degrees)	CK-MA (mm)	CRT-MA (mm)	CKH-R (min)	CFF-MA (mm)	CFF-Fib (mg/dL)
4.6-9.1	0.8-2.1	63-78	52-69	52-70	4.3-8.3	14-31	238-422

Citrated: K, RT, FF cartridge (Lysis cartridge)

CK-R (min)	CK-LY30 (%)	CRT-MA (mm)	CFF-MA (mm)
4.6-9.1	0.0-2.6	52-70	14-31

Interpretation

While TEG 6s testing is orderable in the hospital information system, laboratory policy limits which physicians may order this test. This is a patient safety concern as many physicians do not have the necessary training and experience with TEG 6s to interpret the results. Orders will be taken verbally by approved doctors or their designee only. See Attachment A for approved list of physicians. The order should be placed by lab personnel, and then drawn by the appropriate nurse at the bedside. Requests for interpretation of TEG 6s results previously reported should be referred to the ordering physician who, by virtue of the fact that he/she was able order the test, should be qualified for TEG 6s interpretation. In situations where the ordering physician needs assistance, Haemonetics provides professional support 24x7x365 (1-800-483-2834) with a general turnaround time under 5 minutes.

Maintenance

See approved TEG6s maintenance procedure.

Daily:	Power the TEG® 6s off and on.
Weekly:	Wipe and disinfect all external surfaces with alcohol or disinfectant wipes. **Do NOT use Bleach.**
Monthly:	Remove the fan filter at the rear of each analyzer and clean with water.

Warnings

Samples should NOT be checked for clots using wooden applicator sticks before testing.

Troubleshooting

Power the TEG® 6s off and on to troubleshoot analyzer. *NOTE: If a TEG6s cartridge fails, as indicated by an analyzer error message or aborted run, save the cartridge for troubleshooting by a system engineer and possible reagent credit from Haemonetics.*

References

Haemonetics® TEG® 6s Operators Aide.
TEG® 6s User manual
TEG® 6s Citrated Multichannel Assay Cartridge: K, KH, RT, FF instructions for use
TEG® 6s Citrated Multichannel Assay Cartridge: K, RT, FF instructions for use

Authorized Reviewers

Section Medical or Technical Director

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Document History

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Revised and approved: Steven M. Truscott, PhD Technical Director, STAT Lab Peter Millward, MD Medical Director, Royal Oak	 10/30/2020 10/30/2020	**02**	Incorporated procedures for TEG 6s lysis cartridge and changes for BeakerLIS reporting	
		03	CFF-MA ref range to 14-31 mm for both cartridges	