Beaumont Laboratory
Royal Oak

Effective Date: 11/06/2019
Supersedes: 07/09/2019
Related Documents:
RC.CH.CSL.TEG.PR.001
TEG Approved Physicians

TEG®6s Procedure
Citrated Multichannel Assay Cartridge: K, KH, RT, FF
Royal Oak STAT Lab

RC.CH.CSL.TEG.PR.001r01

Principle
The TEG® 6s System and the Citrated Multichannel Assay Cartridge are used to test the hemostasis properties of citrated blood samples 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).

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 Cartridge with four independent assays (CK, CRT, CKH and CFF) 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. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during, and following the procedure.

Specimen Collection and Handling

For blood draws, use only 3.2% sodium citrate tubes, completely filled. No other tube type is acceptable. After collection, gently invert the tube 5 times. 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 Multichannel Assay Cartridges sealed with dessicant in foil pouch. Cartridges must be refrigerated (2℃ to 8℃) in sealed foil pouches when not in use. Each cartridge contains the following reagents for the indicated channel:

CK (Citrated Kaolin) (Kaolin + $CaCl_2$, for citrated blood) reagent: Dried Kaolin and Calcium Chloride (adequate to reverse citration of the sample).
CRT (Citrated RapidTEG®) (RapidTEG® + $CaCl_2$, for citrated blood) reagent: Dried Kaolin, Tissue Factor and Calcium Chloride (adequate to reverse citration of the sample).
CKH (Citrated Kaolin with Heparinase) (Kaolin + $CaCl_2$ + Heparinase, for citrated blood) reagent: Dried Kaolin, Calcium Chloride (adequate to reverse citration of the sample) and Heparinase (adequate to reverse 5 IU heparin/mL of blood).
CFF (Citrated Functional Fibrinogen) (Tissue Factor (TF) + $CaCl_2$ + ReoPro®, for citrated blood) reagent: Dried Tissue Factor, Calcium Chloride (adequate to reverse citration of the sample) and ReoPro®.

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, consisting of fresh healthy adult donor citrated whole blood (taking no medications known to affect coagulation) and the Haemonetics Abnormal QC (REF 07-662-US).

Abnormal QC Preparation:

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.

Procedure

1. 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.
2. Touch the screen on the front of the instrument to illuminate the panel.
3. Enter **Username** (Beaumont User ID / bh number) and **Password** (specific for the TEG®).
4. Select “new test” on the screen. (QC is tested by selecting “new qc”.)
5. 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”.
6. Select the correct sample identification number from the list. Select “next”.
7. The message “No patient data available” appears. Select “continue”.
8. When prompted, insert the cartridge in the slot on the front of the instrument with the barcode facing to the left.
9. Verify the cartridge with the sample type. (Citrated: K, KH, RT, FF requires Blue top NaCitrate.) Select “next”.
10. Type patient **Last Name** and **First Name** into the Test Information field and select “next”.
11. Ensure that at least 15 minutes has elapsed since collection of the sample.
12. 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”.

13. 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".
14. 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.
15. Depending on clotting time, the assay is completed in 25-40 minutes. The cartridge slot LED will flash, and user is prompted to remove the cartridge when testing is completed.
16. Verify the results in the LIS. If in the event that results look unsuitable to report or have a greater than or less than value, the Medical Technologist will leave the test in the resulting batch, and the STAT Lab MTII or designee will report the results manually.
17. The STAT Lab MTII or designee will print reports daily (Monday-Friday dayshift) and scan to the LIS for reporting in the EMR.

Analytical Measuring Ranges (AMR)

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

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

Reference Ranges

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	15-32	238-422

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 issue 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 (RC.CH.CSL.TEG.PR.001A.r00) 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 back 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 maintenance procedure RC.CH.CSL.TEG.PR.002r00.

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.

Manual Resulting

In order to report results with greater than or less than AMR values, the results from the TEG reports should go directly into the SOFT reporting fields. Report the TEG parameter into the corresponding field in SOFT. Report the extra fields as "**.DNR**".

Field in SOFT	Field in TEG
RTEG	CK-R
KTEG	CK-K
ANTEG	CK-Angle
MATEG	CK-MA
MRTEG	CRT-MA
CKH	CKH-Time
MAFF	CFF-MA
FLEV	CFF-FLEV

Report these fields in SOFT with ".DNR"

RTEG1	.DNR
KTEG1	.DNR
CKH1	.DNR

References

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

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Section Medical or Technical Director

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Number of Controlled Copies posted for educational purposes: 0
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Location of circulating Controlled Copies: n/a

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Robin Carey-Ballough, MT(ASCP) Kelly Walewski, C(ASCP) Steven M. Truscott, PhD, DABCC	06/20/2019	r00		
Approved by: Steven M. Truscott, PhD, DABCC Technical Director, STAT Lab Peter Millward, MD Medical Director, Beaumont Laboratory Mark Smith, MD Medical Director, Coagulation Tim Kennedy, MD Medical Director, STAT Lab	 07/01/2019 07/02/2019 7/01/2019 07/01/2019	r00		
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Revised by: Kelly Walewski, C(ASCP)cm Approved:	10/24/2019	**01**		

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