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TEG® 6s Hemostasis Testing - Point of Care

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform TEG® 6s (TEG) hemostasis and platelet mapping testing procedures to non-laboratory testing personnel.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. The thromboelastograph (TEG) analyzer is indicated for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample at the point of care (POC). The TEG records the kinetic changes in a sample of heparinized or citrated whole blood as the sample clots. The indication for TEG use is with adult patients (18 years and older) where an evaluation of blood hemostasis properties is desired.

B. The Citrated Multichannel Cartridge: CK, CRT, CKH, CFF (purple) is used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions (viscoelastography). The Citrated: CK, CRT, CFF Cartridge (orange) is used to assess clinical conditions in a trauma setting to assess hemorrhage or thrombosis conditions or in liver transplants (viscoelastrography with fibrinolysis).

1. CK (citrated kaolin) monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG. Clotting characteristics are described by the functional parameters R (Reaction time) and LY30 (percent lysis).
2. CRT (citrated RapidTEG™) monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the TEG. Clotting characteristics are described by the functional parameter MA (maximum amplitude).
3. CKH (citrated kaolin with heparinase) monitors the effects of heparin in 3.2% citrated

whole blood specimens on the TEG. CKH is used in conjunction with CK and heparin influence is determined by comparing clotting times (R) between the two tests.

4. CFF (citrated functional fibrinogen) monitors hemostasis of 3.2% citrated whole blood specimens in the TEG after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameter MA.

C. The platelet mapping cartridge is used to assess platelet function. The assay consists of a set of blood modifiers, ADP (adenosine-5'-diphosphate) and AA (Arachidonic Acid) platelet agonists together with ActivatorF (or ActF) which, when used on a heparinized blood sample, can measure the levels of platelet function. This assay specifically determines the MA and the reduction in MA due to genetics, antiplatelet therapy, or surgical procedures, and reports it as percentage of aggregation or percent inhibition.

D. The TEG system consists of an analyzer and disposable assay cartridges. The analyzer contains an interface in the form of a color touch-enabled display. The system is designed to accept a disposable plastic cartridge, into which a blood sample can be placed. Once a test is started, the analyzer processes the sample and reports the results on the touchscreen display.

E. The TEG monitors the harmonic motion of a pendant drop of blood in response to external vibration. As the sample transitions from a liquid state to a gel-like state during clotting, the modulus of elasticity and resonant frequency increase. The analyzer measures these variations in resonant frequency during clotting and lysis and displays the results on a touchscreen display.

F. Disposable cartridges are used for processing whole blood samples. Blood is delivered by transfer pipette to a small port in the cartridge. Once a sample has been added to the cartridge and testing has begun, the sample is inaccessible to the user. The cartridges contain all necessary reagents for performing an assay.

III. DEFINITIONS:

A. R: Reaction time. The amount of time between the start of the test and the beginning of coagulation.

B. K: The speed of formation of the clot from R time to a specific clot strength.

C. Angle: The speed of clot strengthening.

D. MA: Maximum amplitude. The ultimate strength of the clot.

E. LY30: Percent lysis 30 minutes after MA is finalized. 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 finalized.

F. % Inhibition: Indicates the reduction in platelet contribution to overall clot strength. This is displayed in platelet mapping testing.

G. % Aggregation: Indicates the percent of platelets not inhibited, determined by comparing the uninhibited platelet contribution. This is displayed in platelet mapping testing.

H. HKA: Kaolin with Heparinase

IV. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene, as well as any isolation transmission precautions ordered when collecting and handling a blood specimen. Hands must be washed

or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves must be worn when performing patient testing and changed between patients.

A. Patient Preparation
    1. There is no special patient preparation prior to specimen collection, however, multiple items need to be considered prior to collecting TEG samples:
        a. Confirm the instrument is powered on and that the internal quality control (QC) procedures have been performed and are acceptable (see the Quality Control (QC) section below for more information).
        b. Determine if there will be a delay in running the specimen.
            i. Citrated: CK, CKH, CRT, CFF and Citrated: CK, CRT, CFF patient samples should be tested following a minimum of 10 minutes of incubation after collection in citrated tubes. Samples should not be tested more than 4 hours post-collection. See below for more information.
            ii. Platelet Mapping samples should be tested following a minimum 30 minute incubation and within 2 hours of the collection. See below for more information.

B. Patient Identification
    1. Patients must be identified at the bedside using two identifiers (Joint Commission).

C. Specimen Labeling
    1. Since all TEG testing is performed away from the bedside, all samples must be labeled with the patient's name and identification (ID) number. A handwritten or computer-generated patient information label must be placed on the collection tube. If desired, a sample description may be included (i.e. baseline, post incision, on bypass, midpoint, post bypass, post re-perfusion, arterial line, etc.).

D. Specimen Types
    1. Arterial whole blood
        a. Arterial puncture complication verification checks should be documented in the patient's chart (i.e. presence of collateral blood flow, collection site, Modified Allen's test, etc.).
        b. Indwelling line: Do not obtain the sample from a heparinized access line, lock, or indwelling heparin lock. Discontinue the fluid drip, if applicable, prior to collection.
    2. Venous whole blood
        a. See the Venipuncture Techniques procedure for more information.

E. Specimen Collection, Handling, Transportation, and Storage
    1. Prepare the TEG software and confirm QC has been performed and is acceptable.
    2. Verify that the specimen collection supplies are not expired.
        a. **Citrated: CK, CKH, CRT, CFF and Citrated: CK, CRT, CFF** Use only 3.2% sodium

citrate tubes (light blue top). The cartridge box will display the tube type needed for testing.

b. **Platelet Mapping** Use only non-gel heparin tubes with ≥14.5 IU but ≤20 IU heparin/mL of blood (green top). The cartridge box will display the tube type needed for testing.

3. Use a 21 gauge needle.
    a. Smaller needles should not be used. The use of a butterfly needle with tubing is recommended as it puts less pressure on the vein.
4. Draw a discard tube first. Use a no-additive tube or a citrate tube marked "discard". Red top tubes are not acceptable waste tubes as they contain clot activators.
    a. Line draws: Discard 3 times the dead space, typically 10 mL. If the line is extremely long or extremely wide, discard more blood.
5. Switch to the collection tube. Fill the specimen tube completely until the vacuum is exhausted. Short draws are not acceptable.
    a. If collecting using a syringe, pull back gently on the syringe. Pulling hard on the syringe causes shear forces that can affect the TEG results.
6. Label the specimen.
7. Gently invert the tube 5 times to mix.
8. Transport the specimen from the bedside to the testing area immediately.
9. Maintain all specimens at room temperature prior to testing. Let the tube rest horizontally to maintain optimal platelet function.
    a. **Citrated: CK, CKH, CRT, CFF and Citrated: CK, CRT, CFF** Samples should be tested after a 10 minute incubation period and within 4 hours of collection.
        i. In an emergent situation, when speed to results is a concern for patient care, samples may be tested immediately.
    b. **Platelet Mapping** Samples should be tested after a 30 minute incubation period and within 2 hours of collection.
10. Discard all assayed samples in biohazardous waste. Do not save samples for repeat testing.

F. Specimen Acceptability Criteria

1. All specimens should be collected after the instrument has successfully passed internal QC.
2. A minimum of 3 mL of blood must be wasted using an additive-free tube prior to specimen collection.
3. Specimens must be labeled and inverted 5 times immediately after collection.
4. **Citrated: CK, CKH, CRT, CFF and Citrated: CK, CRT, CFF** Collected in 3.2% sodium citrate tubes and tested after 10 minutes but before the 4 hours post-collection time limit has lapsed.
5. **Platelet Mapping** Collected in non-gel heparin tubes with >14.5 IU but <20 IU heparin/mL of blood tested after 30 minutes but before the 2 hours post-collection time limit has

lapsed.

G. Specimen Rejection Criteria

1. Specimens collected without prior blood wasting should be rejected. Blood from the initial draw will contain tissue and/or line contaminants. TEG results may be adversely affected by these contaminants.
2. Any sample collected after a red top activator tube or red top gel tube is used as the discard tube
3. Incompletely filled tubes
4. Clotted or partially clotted blood
5. Samples checked for clots using a wooden stick
6. Refrigerated specimens or specimens stored on ice
7. Citrated: CK, CKH, CRT, CFF and Citrated: CK, CRT, CFF: Collected in anything other than a 3.2% citrate tube and tested more than 4 hours after the specimen was collected
8. Platelet Mapping: Collected in a gel tube, a non-heparin tube, a tube containing too little or too much heparin, a sample tested without a 30 minute incubation period, or a specimen not tested within 2 hours of collection

V. REAGENTS:

A. TEG® 6s Citrated: CK, CKH, CRT, CFF: 10 cartridges and 12 transfer pipettes

1. Availability: Ordered by Comprehensive Care Services staff and stored in the Perfusion department.
2. Contents:
    a. CK: kaolin, calcium chloride
    b. CRT: kaolin, tissue factor, calcium chloride
    c. CKH: kaolin, calcium chloride, heparinase
    d. CFF: tissue factor, calcium chloride, abciximab
3. Storage: Cartridges in sealed foil pouches should be refrigerated at 2-8°C. Cartridges must be protected from temperatures above 35°C.
4. Handling: Remove the cartridge prior to use to allow to equilibrate to room temperature. Cartridges must be used within 2 hours after removal from the pouch and exposure to ambient room temperature.
5. Expiration: Unopened cartridges are stable until the expiration date printed on the packaging when stored at 2-8°C.
6. Warnings/Precautions: For *in vitro* diagnostic use only. Cartridges are single use only. Dispose of the used cartridge in a biohazard container or biohazard sharps container.

B. TEG® 6s Citrated: CK, CRT, CFF: 10 cartridges and 12 transfer pipettes

1. Availability: Ordered by Comprehensive Care Services staff and stored in the Perfusion department.

2. Contents:
    a. CK: kaolin, calcium chloride
    b. CRT: kaolin, tissue factor, calcium chloride
    c. CFF: tissue factor, calcium chloride, abciximab
3. Storage: Cartridges in sealed foil pouches should be refrigerated at 2-8°C. Cartridges must be protected from temperatures above 35°C.
4. Handling: Remove the cartridge prior to use to allow to equilibrate to room temperature. Cartridges must be used within 2 hours after removal from the pouch and exposure to ambient room temperature.
5. Expiration: Unopened cartridges are stable until the expiration date printed on the packaging when stored at 2-8°C.
6. Warnings/Precautions: For *in vitro* diagnostic use only. Cartridges are single use only. Dispose of the used cartridge in a biohazard container or biohazard sharps container.

C. TEG® 6s PlateletMapping® ADP & AA: 10 cartridges and 12 transfer pipettes
1. Availability: Ordered by Comprehensive Care Services staff and stored in the Perfusion department.
2. Contents:
    a. HKH: kaolin, heparinase
    b. ActF: ActivatorF, Abciximab
    c. ADP: ADP, ActivatorF
    d. AA: AA, ActivatorF
3. Storage: Cartridges in sealed foil pouches should be refrigerated at 2-8°C. Cartridges must be protected from temperatures above 35°C.
4. Handling: Remove the cartridge prior to use to allow to equilibrate to room temperature. Cartridges must be used within 2 hours after removal from the pouch and exposure to ambient room temperature.
5. Expiration: Unopened cartridges are stable until the expiration date printed on the packaging when stored at 2-8°C.
6. Warnings/Precautions: For *in vitro* diagnostic use only. Cartridges are single use only. Dispose of the used cartridge in a biohazard container or biohazard sharps container.

D. Cartridge Reagent QC-Level 1: 12 QC vials and 12 diluent water vials
1. Availability: Ordered by Comprehensive Care Services staff and stored in the Perfusion department.
2. Contents: Bovine plasma, tissue factor, anticoagulant
3. Storage: Sealed vials should be refrigerated at 2-8°C.
4. Handling: Reconstituted QC materials must be used within 2 hours of reconstitution.
5. Expiration: Unopened QC vials are stable until the expiration date printed on the

packaging when stored at 2-8°C.

6. Warnings/Precautions: For *in vitro* diagnostic use only. QC materials are single use only. Dispose of the QC in a biohazard container or biohazard sharps container.

E. Cartridge Reagent QC-Level 2 12 QC vials and 12 diluent water vials

1. Availability: Ordered by Comprehensive Care Services staff and stored in the Perfusion department.
2. Contents: Bovine plasma, tissue factor, tissue plasminogen activator
3. Storage: Sealed vials should be refrigerated at 2-8°C.
4. Handling: Reconstituted QC materials must be used within 2 hours of reconstitution.
5. Expiration: Unopened QC vials are stable until the expiration date printed on the packaging when stored at 2-8°C.
6. Warnings/Precautions: For *in vitro* diagnostic use only. QC materials are single use only. Dispose of the QC in a biohazard container or biohazard sharps container.

F. Normal Donor (Platelet Mapping)

1. Screen the donor to verify that the donor is not taking any medication that will affect the MA results. Donors with bleeding disorders, are pregnant, taking birth control pills or hormone-based medication, or are taking any of the medications in the list below should be excluded as a normal donor.

Donor Coagulation-Affecting Medication Reference List

Neutraceuticals/Supplements	Omega-3 Fish Oil Garlic Ginseng Ginkgo Ginger Green Tea St. John's Wort Saw Palmetto
NSAID	Aspirin Ibuprofen Naproxen Diclofenac (Voltaren®) Piroxicam (Feldene®)
Anti-Platelet Medications	Clopidogrel (Plavix®) Prasugrel (Effient®) Ticagrelor (Brilinta®)
All STATINS	Atorvastatin Simvastatin Rosuvastatin Lovastatin
Antihistamines	Chorpheniramine (Clor-trimeton®)

	Dihenhydramine (Benadryl®)
SSRI Antidepressants	Prozac® (Fluoxetine) Zoloft® (Sertraline) Celexa® (Citalopram) Lexapro® (Escitalopram)
Tricyclic Antidepressants	Amitripyline (Elavil®, Endep®, and others) Imipramine (Tofranil®) Nortriptyline (Pamelor®, Aventyl®)
Some Antibiotics	All penicillins and amoxicillins Sulfonamides Cloramphenical Vancomycin
Cardiovascular/Blood Pressure Medications	Nitrprusside Nitrglycerin Metoprolol Atenolol Propranolol Nebivolol Pindolol Verapamil Nifedipine Diltiazem
Anticoagulants	Heparin Low Molecular Weight Heparins (Lovenox® and other brands) Warfarin (Coumadin®) Dabigatran (Pradaxa®) Rivaroxaban (Xarelto®) Apixaban (Eliquis®)

2. Draw a discard tube followed by a 3.2% citrate tube.
3. Label the tube as "normal donor".
4. Gently mix 5-7 times then allow the tube to rest horizontally for 30 minutes to 2 hours.

G. Abnormal Donor (Platelet Mapping)

1. Screen the donor. The donor may take clopidogrel or aspirin.
2. Draw a discard tube followed by a non-gel heparin tube.
3. Gently mix the tube 5 times then allow the tube to rest horizontally for 30 minutes.
4. If an abnormal donor cannot be found, spike the blood with aspirin (see the QC section below for more information).

H. 325 mg Aspirin Tablet

1. Availability: Obtain from site-specific Pharmacy department.

2. Contents: Acetylsalicylic acid
3. Storage: Sealed pouches should be stored at room temperature (approximately 20-25°C). Store away from moisture, heat, and direct light. Do not freeze.
4. Handling: Discard aspirin-saline solution after testing is complete. Do not store solution for more than 24 hours.
5. Expiration: Unopened aspirin pouches are stable until the expiration date printed on the packaging when stored at room temperature.

I. Saline

1. Availability: Obtain an aliquot from site-specific Laboratory.
2. Contents: Sodium chloride
3. Storage: Store the aliquot of saline at room temperature (approximately 20-25°C).
4. Handling: Discard aspirin-saline solution after testing is complete. Do not store solution for more than 24 hours.
5. Expiration: Unopened bottles of saline are stable until the expiration date printed on the bottle when stored at room temperature.

VI. EQUIPMENT/SUPPLIES:

A. Personal Protective Equipment (PPE)
B. Blood Collection Supplies
C. 70-95% Isopropyl Alcohol or PDI Super Sani-Cloth® (Maintenance)
D. Biohazard Receptacle or Biohazard Sharps Container
E. Clock/Watch/Timer (Liquid QC and Patient Sample Incubation Timing)
F. Test Tube/Small Mixing Tube/Sterile Urine Cup (Platelet Mapping Abnormal QC with Aspirin)
G. Disposable Pipettes (QC Reconstitution/Platelet Mapping Aspirin QC Preparation)

VII. CALIBRATION/CALIBRATION VERIFICATION:

A. The TEG does not require routine calibration.
B. Calibration verification is performed at least approximately every 6 months (usually after preventative maintenance) by running two levels of liquid controls for each parameter on every instrument in use. Calibration verification is performed prior to assigning a new analyzer for patient testing, when QC samples demonstrate a shift or trend or fall outside of the acceptable range, and after major maintenance or service repairs.
C. Control materials used for calibration verification are assayed in the same manner as liquid QC samples.
   If the calibration verification results fall outside of the acceptable ranges, the instrument will be removed from clinical use until corrective action resolves the issue.
D. Document the data on the TEG 6s Calibration Verification Log.
   1. If any of the data is unacceptable, the instrument should not be used for testing until the issue is resolved. Refer to the Quality Control (QC) section below for the procedural steps and information regarding failed QC/calibration verification steps.

VIII. INSTRUMENT COMPARISONS:

A. Instrument comparisons using patient samples and/or QC are performed to verify instrument result correlation with TEG parameters. Instrument comparisons are only performed at sites with more than one TEG instrument.

B. Twice per year, approximately every six months, POC and/or Perfusion staff will compare the instruments using samples with both normal and abnormal values.

C. Follow the steps in the Procedure section below and record the results on TEG 6s Instrument Comparison form.

    1. If any of the comparison data is unacceptable, the instruments should not be used for patient testing until the issue is resolved.

IX. NEW LOT VALIDATION:

A. External QC is performed to verify that cartridges have not been mishandled between production and arrival at the laboratory/perfusion department or have not been subject to adverse environmental conditions or otherwise mishandled while in storage. QC will be performed on each new lot/shipment of assay cartridges.

B. Document results on the TEG 6s New Lot Validation form.

X. MAINTENANCE:

A. Cleaning and Disinfecting the Analyzer

    1. The surfaces of the TEG must be wiped down and disinfected weekly, or more frequently if the instrument is visibly dirty.

        a. Turn off the analyzer and unplug it from the wall before cleaning.

        b. Use gauze pads soaked in isopropyl alcohol, isopropyl wipes, or PDI Super Sani-Cloth® wipes to clean all external surfaces including the touchscreen.

            i. Do not spray or immerse the analyzer in any solution.

            ii. Do not clean the analyzer with acetone or any other plastic solvent or abrasive cleaner.

            iii. Do not clean the analyzer with bleach.

            iv. Avoid getting liquid into the cartridge slot at the front of the analyzer or into the connectors on the rear panel.

        c. Dispose of gauze/wipe in a biohazard container.

        d. Record on the TEG 6s QC and Maintenance log.

B. Cleaning the Filter

    1. The filter at the rear of the instrument should be cleaned or replaced during the annual preventive maintenance (PM) by Haemonetics personnel. However, if a temperature error occurs before a scheduled PM, clean the filter.

        a. Grasp the edges of the filter cover and pull to remove it.

        b. Remove filter from the cover.

c. Rinse the filter under warm running water until it is clean. Do not use soap or any cleaning solution.

d. Squeeze out excess water. Place on a clean cloth and allow to dry completely.

e. Verify that the filter is 100% dry, then reinsert it into the filter cover.

f. Press the filter cover back onto the analyzer.

g. Record on the TEG 6s QC and Maintenance log under the "additional maintenance as needed" column.

C. Preventative Maintenance (PM)

1. Haemonetics staff will perform a PM on an annual basis. Copies of the PM documentation will be stored in the site-specific POC department.

D. TEG Manager Data Log Pull

1. The TEG Manager software will automatically delete analyzer log data that has already been captured by the TEG Manager to minimize the log file size on the analyzers. This task occurs overnight and will cause the instruments to be locked for approximately 1 minute.

E. POC Staff Only

1. Operators with administrator privileges can use a Haemonetics USB key to access the maintenance screen to perform additional troubleshooting and maintenance as directed by the analyzer and/or Haemonetics staff.

F. Emergency Shutdown

1. If testing is in progress, press "Stop" on the "Results" screen.
2. In the confirmation message, touch "Acknowledge" to stop the test.
3. Confirm any existing cartridge has been removed from the cartridge slot.
4. Logout of the instrument (see Procedure section below).
5. It is safe to turn off the analyzer from the login screen. To do this, move the power switch at the back of the instrument to the "O" position.

XI. QUALITY CONTROL (QC):

A. Internal QC

1. The TEG is designed with the following internal, built-in QC features that verify that all the electromechanical and pneumatic functions and analyzer-cartridge combination are operating satisfactorily.

a. Power On Self Test (POST): When the power switch is moved to the "on" position, the analyzer initiates the POST sequence. This performs QC tests on all analyzer functions prior to cartridge insertion. A failure of any component will report an error on the display screen and prevent further operation.

b. Pre-Test: When a cartridge is inserted into the slot, the analyzer performs a pre-test QC to verify the barcode reader's ability to identify the cartridge and the integrity of the cartridge-analyzer interface. A failure of any component will report an error on the display screen and prevent further operation.

c. In-Use: When the user adds the sample and starts the test, the analyzer's internal QC functions monitor critical operational parameters throughout the duration of the test. At every step, if any critical operational parameter is found to be out of range, it will be reported and the test will be invalidated.

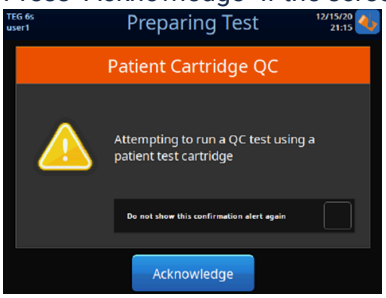
B. External QC

1. Two levels of TEG QC solutions are tested at least once per 30 days on each cartridge type in use, to validate new lots and/or shipments of cartridges, to troubleshoot instrument problems, and after the instrument has been serviced, or recalibrated.
2. External QC Procedure
    a. Detailed analyzer operation instructions may be found in the Procedure section below.
    b. Initialize the analyzer.
    c. Prepare the QC sample.
        i. CK, CKH, CRT, CFF and CK, CRT, CFF Cartridges
            a. Allow one QC vial and one diluent water vial to sit for approximately 10 minutes to equilibrate to room temperature.
            b. Visually inspect the QC vial to confirm the lyophilized material is on the bottom of the vial. If necessary, tap the vial a few times to move the lyophilized material to the bottom.
            c. Remove the seal and stopper of the control vial.
            d. Slowly and carefully pour the contents of the diluent water vial into the control vial. Confirm that no water drips out and no water droplets are left in the diluent vial or the cap of the diluent vial.
                i. Alternatively, use a disposable pipette to aspirate the contents of the diluent vial and dispense into the control vial.
            e. Reinsert the stopper into the control vial.
            f. Hold the stopper in place and vigorously shake the control vial for 15 seconds. Allow the vial to stand for 5 minutes at room temperature.
            g. Vigorously shake the control vial AGAIN for 15 seconds and allow to stand an ADDITIONAL 5 minutes. Visually inspect the vial to confirm that there is no undissolved material remaining in the vial. The QC material should be clear, not cloudy, and have no visible particles. Repeat this mixing step, if needed.
                i. Reconstituted QC must be used within 2 hours of reconstitution.
        ii. Platelet Mapping Cartridges

a. Normal Donor Control
    i. Collect a sample as indicated in the Reagents section above.

b. Abnormal Donor Control
    i. Collect a sample as indicated in the Reagents section above. If an abnormal donor is not available, create an abnormal sample by following the instructions below.
        i. Crush one 325 mg aspirin tablet.
        ii. Add the aspirin powder to a labeled container with approximately 60 mL of normal saline.
        iii. Swirl the solution for 5 seconds every 10 minutes for 30 minutes.
        iv. Add approximately 0.5 mL of the aspirin solution to a 4 mL tube of heparinized blood.
        v. Recap the tube and gently mix 5-6 times. Label the tube "aspirin sample".
        vi. Incubate the tube horizontally at room temperature for 30 minutes.
        vii. Gently mix the aspirin specimen 5 times prior to testing.

d. Remove the cartridge from the refrigerator and allow to equilibrate to room temperature.
e. From the "Home" screen on the TEG, select "New QC".
f. Insert the cartridge into the slot as indicated on the screen.
g. Press "Acknowledge" if the screen below appears.

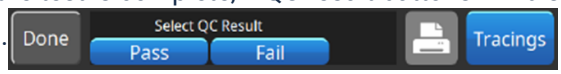


TEG® 6s Hemostais System User Manual, Haemonetics Corporation

h. On the "QC Level" screen, select the QC test needed (L1-Normal or L2-Abnormal) and press "Next".
i. Enter QC test information on the "Test Information" screen and touch the "Next" button.
j. Pipette the prepared QC sample into the cartridge sample port.

k. Press "Start Test".

Run Type	Cartridge Type	Approximate Run Time
QC Level 1	K, KH, RT, FF (Purple)	24-26 minutes
QC Level 2	K, KH, RT, FF (Purple)	7-8 minutes
QC Level 1	K, RT, FF (Orange)	55-56 minutes
QC Level 2	K, RT, FF (Orange)	35-38 minutes
Normal Donor	Platelet Mapping	20-45 minutes
Abnormal Donor/Normal Donor with Aspirin	Platelet Mapping	20-45 minutes

l. When the test is complete, 2 QC result buttons will display at the bottom of the screen. 

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i. Compare the results to the manufacturer's acceptable ranges outlined in the package insert for the Citrated: CK, CKH, CRT, CFF and Citrated: CK, CRT, CFF cartridges. Compare the Platelet Mapping normal donor results to patient normal reference ranges. See the Expected Values section below.

ii. If all results fall within the acceptable ranges, press "Pass". If one or more results falls outside the ranges, press "Fail".

iii. Press "Acknowledge".

m. Remove the cartridge when prompted and discard into a biohazard container. Discard QC vials, cartridges, and pipettes in a biohazard container.

n. Touch "Done" to return to the "Home" screen.

3. QC Failure Procedure

a. Verify cartridge and control are not past expiration dates.

b. Confirm proper temperature and humidity storage for supplies.

c. Confirm that the proper procedure was followed.

d. Repeat with a new cartridge and new QC solution.

e. If QC still fails, label the analyzer clearly with “Do not use for patient testing”.

i. Follow the site-specific instructions below for assistance:

a. Dearborn: Call Perfusion at 947-522-9766 or 313-593-5988.

b. Royal Oak: Call Ancillary Testing at 248-898-8012.

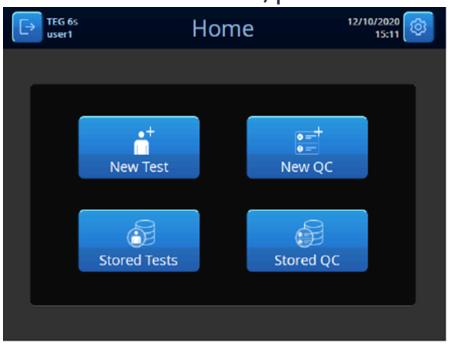
c. Troy: Call Decentralized Testing at 248-964-8009.

4. Viewing QC Results
    a. Previously performed QC may be viewed from the "Home" screen by touching "Stored QC".
    b. Select the appropriate QC run then touch "Results".
    c. The status of each test is shown on the right side of the screen. A green check mark indicates that the test completed (all parameters were finalized), a red X indicates that the test timed out. An orange triangle indicates that the test was stopped early.

XII. PROCEDURE:

A. Analyzer Initialization
    1. To turn on the analyzer, move the power switch at the rear of the analyzer from the "O" to the "I" position. After a brief startup sequence, the device executes a Power On Self Test (POST).
    2. The login screen will appear after a successful POST. Enter the user name on the touchscreen keyboard or via the hand-held barcode scanner.
    3. Move the cursor to the password box by pressing the password box or using the return key [↵].
        a. Note: Depending on the operator-specific user role assigned, password entry may not be required.
    4. Enter the password then press "Login".
    5. Review the icons at the top of the screen. Address any alert icons displayed before proceeding with patient testing.
        a. Note: Alert icons displayed on pop-up messages prove an indication of severity.
        b. See the Troubleshooting section below for descriptions of the icons.

B. TEG Software Set-up
    1. On the "Home" screen, press "New Test".



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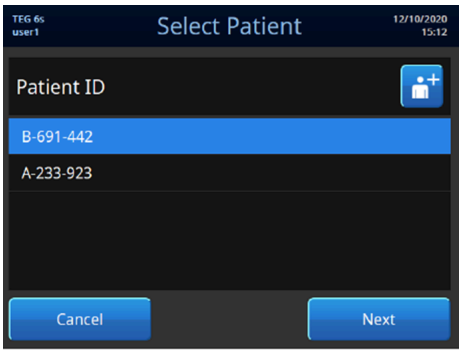
    2. On the "Select Patient" screen, select the patient to be tested. If the patient is not listed, press the "Add Patient" button and enter the patient's medical record number (MRN). Press "Confirm" then press "Next".



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3. The TEG Manager will send positive patient identification (PPID) information to the instrument. Review the information and press "Confirm" if the correct patient is listed. If the incorrect patient information is displayed, press "Reject" and reenter the patient's ID.
4. Insert the cartridge into the slot, as indicated on the screen, with the barcode facing left.
    a. Note: Do not remove the cartridge until prompted to do so either after normal completion of the test or as a result of choosing to stop the test.
5. Confirm that the cartridge type is correct for the testing indicated and press "Next".
    a. Note: The color of the test tube displayed on the "Preparing Test" screen indicates the type of specimen to be used for the test selected.
6. On the "Test Information" screen, enter information for the test (e.g. baseline, post-incision, on-bypass, midpoint, post-bypass, post re-perfusion, arterial line, etc), if desired, then touch the "Next" button.
    a. Note: Do not enter protected health information (PHI) in the test information field as this information is not encrypted when stored locally.
7. When "Load Sample" appears, gently mix the tube 5-7 times then add blood to the cartridge sample port, filling up to or above the line marked on the cartridge, then press "Start Test".
    a. Note: Precise measurement is not necessary. Any excess sample is moved to a sealed waste area within the cartridge during the test. The use of non-class A measuring devices for testing has been approved by the manufacturer.
    b. Most testing errors appear within the first 30 seconds of test initiation. Remain by the instrument during the initial phase of testing (30 seconds) to verify that no problems exist before leaving the TEG area. If an error message appears, repeat the test using a new cartridge.
8. View the test results while testing is in progress, if desired, by following the steps in the Result Review section below.
9. A patient test stops automatically when the requisite parameters for the test have finalized. If not all parameters are required by the clinician, the operator may stop a test early. To manually stop a test:
    a. Navigate to the results screen.
    b. Touch "Stop".
    c. In the confirmation message, press "Acknowledge" to stop the test or touch

"Cancel" to continue without stopping.

10. When the test is complete, the following changes occur on the results screen:
    a. The test timer is replaced by the date and time that the test started.
    b. The progress panel displays the test completion status.
    c. The "Stop" button is replaced by a "Done" button.
    d. The print button  is enabled.
11. Remove the cartridge when prompted by the analyzer. Discard the cartridge and pipette in biohazard waste.
    a. Note: A flashing light at the cartridge slot also indicates that it is safe to remove the cartridge.
12. Touch "Done" to return to the "Home" screen.
13. Upon testing completion, log out by touching the logout button  on the home screen.

C. Analyzer Shutdown
    1. After testing is complete, confirm any existing cartridge has been removed from the cartridge slot.
    2. Logout of the instrument (see above).
    3. It is safe to turn off the analyzer from the login screen. To do this, move the power switch at the back of the instrument to the "O" position.

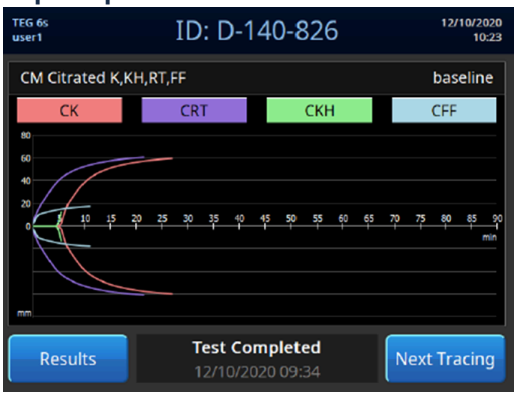
XIII. RESULT REVIEW:

A. Prior to reviewing results and tracings for the first time, personnel should view the TEG 6s Clinical Training and TEG 6s Clinical Assessment module at https://hospital.haemonetics.com/login-form?trainingurl=/hospital-trainings .
    1. User name: BHS
    2. Password: teg75

B. Viewing Stored Patient Data on the TEG Instrument
    1. Each TEG instrument stores approximately 100 tests in its database.
    2. Press "Stored Tests" on the "Home" screen.
    3. On the "Stored Tests" screen, select the desired test.
        a. Note: The status of each test is shown on the left side of the screen. A green check mark icon indicates that the test completed (all parameters were finalized), a red exclamation point icon indicates that the test is incomplete due to an error or timeout, and and orange incomplete icon indicates that the test was stopped early. See the icons below in the Troubleshooting section.
    4. Touch "Details" to view the result for each test.
    5. If desired, view the tracings by pressing the "Tracings" button.
        a. Superimposed and individual-channel tracings display a Y axis that indicates the amplitude (in milimeters). All tracing modes display an X axis that indicates

the time (in minutes).

Superimposed



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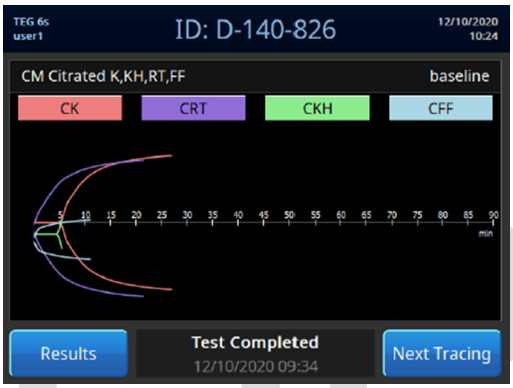
Offset



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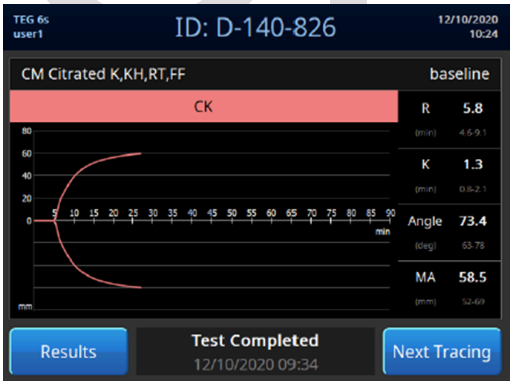
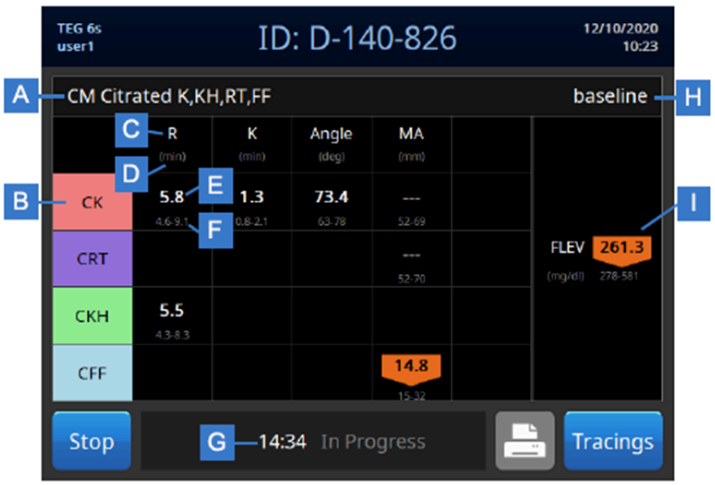
Individual-channel



TEG® 6s Hemostais System User Manual, Haemonetics Corporation

6. Press the "Print" button to print results for the patient, if a paper copy is needed.
7. Touch "Back" to return to the "Stored Tests" screen or "Home" to return to the home screen.
8. Results Screen Illustration

C.



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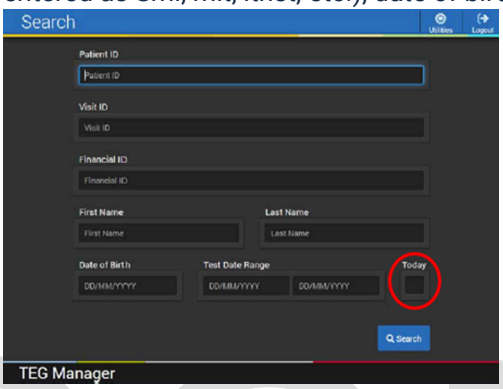
1. A: Cartridge name: This is the name that appears on the outside of the cartridge.
2. B: Test name: Each test name (one per channel) is displayed in the left column. Touch the test name to display the tracing for the test.
3. C: Test parameters: The top row displays the primary parameters that are being measured for each test.
4. D: Parameter units: The units of measure are displayed under each parameter name.
5. E: Parameter values:
    a. The large numbers indicate the results of each test.
    b. A parameter displays with dashed lines until it is finalized and a numerical result appears.
    c. Not all parameters are applicable or calculated for all tests. Any parameter that is not calculated for a test remains blank.
    d. A parameter displays with an asterisk if it cannot be defined due to the timing or value of the MA parameter.
    e. If a finalized parameter falls outside of the reference range, it is displayed with an orange chevron. The chevron point faces up if the parameter falls outside the high end of the range or down if it falls outside the low end of the range.
6. F: Reference ranges: The maximum and minimum limits for normal results for each parameter appear under the parameter values.
7. G: Test timer: The timer begins when the test starts. Once the assay is complete, the timer stops and is replaced by the date and time that the test started.
8. H: Test information: The information that is added for the test in the "Test Information" screen displays at the top right of the screen.
9. I: Additional parameters: If additional parameters are calculated for any test, they display in the right column.

D. Viewing Results Via TEG Manager Software (Viewer Module)

1. The TEG Manager stores results for the life of the associated TEG instrument(s).
2. Clinicians may review and interpret TEG results in real time.
3. Open the TEG Manager software from https://teg6mgrsqL-p01.bh.beaumonthealth.org/.
4. Enter the user name and password and press "Login".
5. On the "Search" screen, place a ✓ in the "Today" box to look for all the results from the current day. Alternately, search by patient ID (MRN), visit ID (contact serial number (CSN)), patient name (either part or all of the name, for example Smithston can be entered as Smi, mit, ithst, etc.), date of birth, or test date range. Then press "Search".



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6. A maximum of 100 relevant results will be displayed on the "Search Results" screen. The "Test Date" column displays the date of each patient's most recent test.
7. After selecting a patient from the "Search Results" screen, the test results will be displayed.

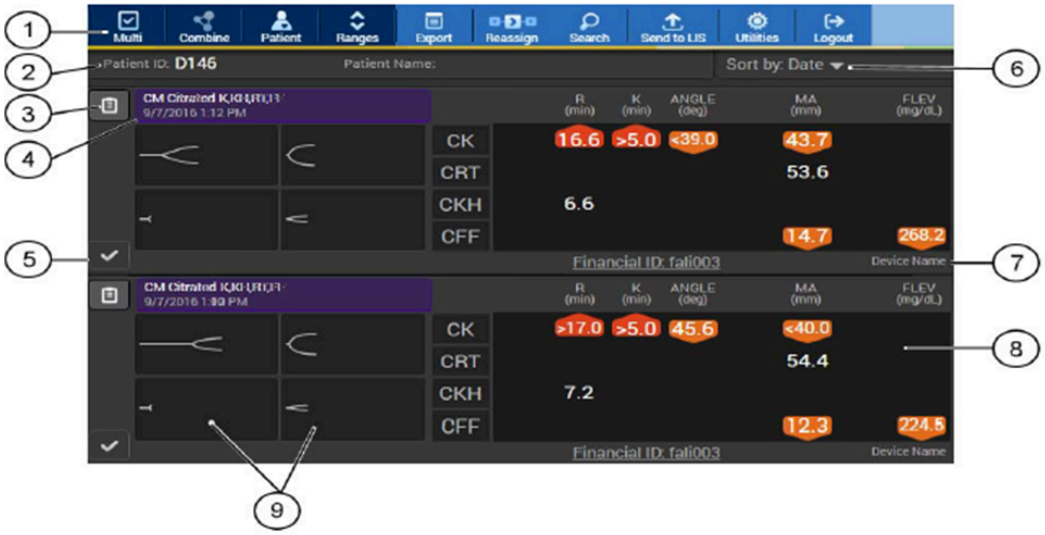

Figure 4, Main screen overview

Legend

1. Toolbar
2. Patient information
3. Charting Notes icon
4. Cartridge name and test date
5. Test indicator icon
6. Sort menu
7. Device name
8. Parameters table
9. Single tracings

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8. The operator may choose to press the "Multi" button to select multiple tests and combine them into a tracing composite or use the "Combine" button to compare multiple tests results when more than one test is selected.
9. The "Information" button is displayed when the Platelet Mapping cartridge is run. Click this button to display the percent inhibition/aggregation results.

XIV. INTERPRETATION OF RESULTS:

A. No calculations are necessary to obtain test results.

   1. Note: Split R's are not expected on the TEG 6s. However, biphasic tracings may occur with the AA assay. If there is a concern of a Split R, repeat the test using a fresh sample or call the site-specific POC department.

B. Each parameter represents a different aspect of the patient's hemostasis:

   1. R: Kaolin R is the time in minutes elapsing between sample activation and the point in time where clotting provides enough resistance to produce a 2 mm amplitude reading on the TEG tracing. The CK-R parameter represents the initiation phase of coagulation triggered by enzymatic clotting factors and culminating with the initial fibrin formation. A prolonged R value is indicative of slow clot formation and a shortened R value is indicative of a fast clot formation.

      a. A prolonged R value is indicative of slow clot formation due to coagulation factor deficiencies or heparin. An elongated R means that it takes longer for the first fibrin strand to be formed and represents a factor deficiency and can

be corrected by administering fresh frozen plasma (FFP).

b. A shortened CK-R time has been observed in patients post traumatic injury.

2. K: A measure of the time it takes from R (beginning of clot formation) to the time it takes to reach a clot strength of 20 mm amplitude. K is shortened by increased fibrinogen level and, to a lesser extent, platelet function and is prolonged by anticoagulants that affect both.

    a. An elongated K and reduced α represents a low level of fibrinogen (factor XIII is rarely deficient) and can be corrected by administering cryoprecipitate or FFP. K is prolonged by anticoagulants that affect fibrinogen and platelet function.

3. Angle: The speed of fibrin build-up/clot development. The angle is closely related to K-time, since they are a function of the rate of clot strengthening. The angle is more comprehensive than K-time, since there are hypocoagulable conditions in which the final level of clot firmness does not reach an amplitude of 20 mm (in which case K is undefined). Similar to K, angle is larger by increased fibrinogen levels and, to a lesser extent, by platelet function, and is decreased by anticoagulants that affect both.

    a. An elongated K and reduced Angle represents a low level of fibrinogen (factor XIII is rarely deficient) and can be corrected by administering cryoprecipitate or FFP.

4. MA: MA is the point of maximal amplitude of the TEG tracing, measured in mm, and reflects the maximum clot strength. The strength of the clot is primarily a result fo platelet-fibrin interactions via the GPIIb/IIIa receptors.

    a. A decreased MA is indicative of low clot strength, which could be due to decreased platelet contribution or decreased fibrinogen, whereas an increased MA is indicative of high clot strength which could be due to increased platelet function.

    b. In the case of cardiac surgery when MA is small, infusion with platelets alone will correct the coagulopathy in most cases because platelets are affected by most, if not all, cardiac surgical procedures. If MA is small, treat with platelets (platelet units also contain fibrinogen). After 10-15 minutes, perform another TEG analysis. If the tracing still shows abnormal (K, Angle), follow the platelet infusion with cryoprecipitate.

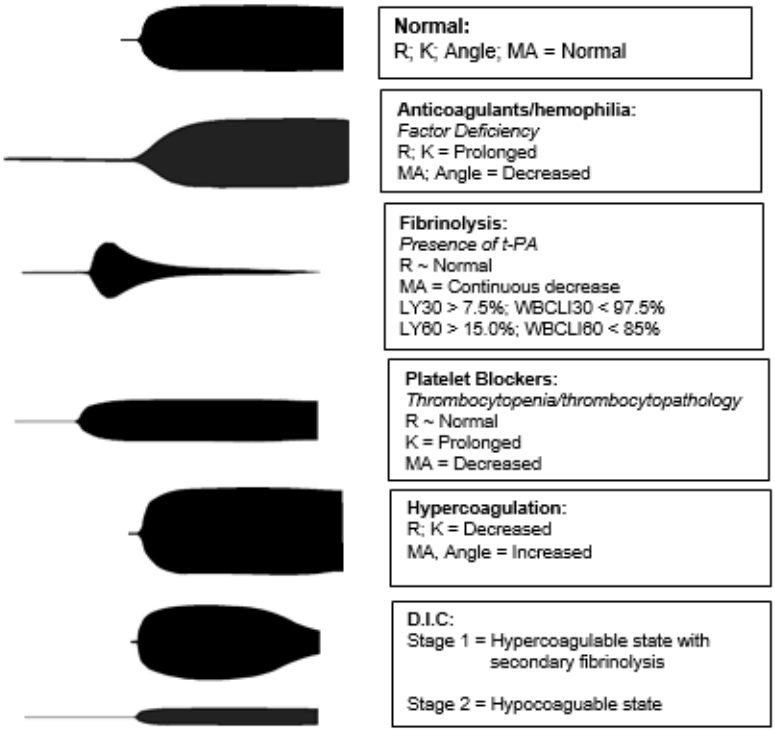
5. CFF: The functional fibrinogen reagent inhibits platelet aggregation via the GPIIb/IIIa receptor, excluding its contribution to clot strength (MA), and thereby primarily measures the functional fibrinogen contribution to clot strength.

    a. CFF provides the overall contribution of fibrinogen and/or platelet contribution to clot strength. In conjunction with MA, this assay enables the contributions of fibrin and platelets to clot strength to be determined.

6. LY30 (Royal Oak Only): Kaolin LY30 is the percent lysis based on the reduction of the tracing area that occurs between the time MA is measured until 30 minutes after the MA is defined. After the clot has formed, it is degraded by fibrinolytic factors within the blood and consequently the amplitude decreases over time. By measuring the extent of amplitude reduction over time, clot lysis can be assessed.

7. The TEG tracing can be qualitatively or quantitatively analyzed. The patterns are easily interpreted without measurement to determine the conditions of hyper-, hypo-, normal

coagulation, and fibrinolysis. However, by using the measurements and established normal ranges and indices, the patterns can be quantified as to the degree of abnormality.



TEG 5000 System User Manual for Clinical Use Indications

XV. RESULT REPORTING:

A. Tracings may be viewed in the TEG Manager software while the test is running and upon completion: https://teg6mgrsqL-p01.bh.beaumonthealth.org/.

1. Dearborn: Report all test results to the ordering physician or authorized person in a timely manner. Recheck abnormal values and report immediately. Record the patient results in the chart with the date, time, and operator's identification.
2. Royal Oak: Once the test is completed, Perfusion staff will print 2 copies of the tracing, sign them, and place one copy in the patient's chart and the other is placed in an envelop for Ancillary Testing staff. (The date and time stamp will be on the print-out).
3. Troy: Once the test is completed, Perfusion staff will print 2 copies of the tracing, sign them, and place one copy in the patient's chart and the other is placed in an envelop for Decentralized Testing staff. (The date and time stamp will be on the print-out).

XVI. REPORTABLE RANGES/ANALYTICAL MEASUREMENT RANGES (AMR):

A. The following table outlines the AMR for the TEG. Results that are above or below the reportable range will display with > or < symbols respectively. Where printing is available, an "!" will print next to the value that is outside the reportable range.

1. Note: If one or more of the MA values are outside the AMR limits, the corresponding

percent inhibition, percent aggregation, and FLEV values will not calculate and will not be displayed.

Reagent	Parameter	Range
CK	R (min) K (min) A/Angle (degrees) MA (mm) LY30 (%)	0.4-17 0.5-5 39-83 40-75 0-22
CRT	MA (mm)	40-75
CKH	R (min)	0.3-17
CFF	MA (mm) FLEV/Fibrinogen (mg/dL)	4-52 130-950
HKH	MA (mm)	42-71
ActF	MA (mm)	2-30
ADP	MA (mm) % Inhibition % Aggregation	10-72 0-100 0-100
AA	MA (mm) % Inhibition % Aggregation	8-76 0-100 0-100

XVII. EXPECTED VALUES:

A. **Citrated: CK, CKH, CRT, CFF**

Assay	Citrated Blood Parameter	Range
CK	R (min) K (min) A/Angle (deg) MA (mm)	4.6-9.1 0.8-2.1 63-78 52-69
CRT	MA (mm)	52-70
CKH	R (min)	4.3-8.3
CFF	MA (mm) FLEV/Fibrinogen (mg/dL)	14-31 238-422

B. **Citrated: CK, CRT, CFF**

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

C. **Platelet Mapping**

Assay	Heparinized Blood Parameter	Range
HKH	MA (mm)	53-68
ActF	MA (mm)	2-19
ADP	MA (mm) % Inhibition % Aggregation	45-69 0-17 83-100
AA	MA (mm) % Inhibition % Aggregation	51-71 0-11 89-100

XVIII. SYSTEM DOWNTIME:

A. Results may be obtained from the instrument, instrument print-out, or TEG Manager software. See the Result Review section above.

B. During an instrument downtime, specimens may be sent to the main laboratory if the TEG remains inoperable. The following tests may be ordered (where available) in place of the TEG test at the surgeon's discretion: PT, PTT, Fibrinogen, Euglobulin Lysis Time, D-Dimer, platelet function, or a TEG 6s assay (Royal Oak STAT Lab only).

C. Once an information technology-related downtime is resolved, the instrument will automatically re-sync and send data to the TEG Manager software.

XIX. LIMITATIONS:

A. The instrument operating temperature is 10-32°C (50-89.6°F).

B. The operating humidity is 20-80%.

C. TEG results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patient's clinical status, samples should be repeated or supplemented with additional laboratory tests and clinical information.

D. Wear powder-free gloves while operating the TEG.

E. Use only the transfer pipettes contained in the test kit. Do not reuse pipettes. The use of non-class A measuring devices for testing has been approved by the manufacturer for patient and QC testing.

F. The instrument will not permit the use of expired cartridges nor will it allow the use of cartridges that have been dosed with QC or a specimen.

XX. INTERFERING SUBSTANCES:

A. Red top tubes contain clot activators that will cause an artificially shortened R time.

B. Citrated: CK, CKH, CRT, CFF Assay

1. CK: Potential interfering factors tested were absence of a discard tube, short draw, hemolysis, hemodilution, and epsilon aminocaproic acid. Only hemolysis and hemodilution levels above 20% were found to be interfering factors.
2. CRT: Potential interfering factors tested were absence of a discard tube, short draw,

hemolysis, hemodilution, and epsilon aminocaproic acid. Only hemolysis and hemodilution above 30% were found to be interfering factors.

3. CKH: The potential interfering factor tested was protamine. Results show that protamine is an interfering factor a concentrations above 0.062 mg/mL.
4. CFF: Potential interfering factors tested were heparin and hemodilution. Heparin was found to be an interfering factor for functional fibrinogen above heparin concentrations of 1 IU/mL and hemodilution was found to be an interfering factor above hemodilution levels of 40%

C. Citrated: CK, CRT, CFF Assay

1. CK: Potential interfering factors tested were absence of a discard tube, short draw, hemolysis, hemodilution, direct oral anticoagulants (FXa and direct thrombin inhibitors), and antiplatelet drug (P2Y12 inhibitor). None were found to be interfering factors.
2. CRT: Potential interfering factors tested were absence of a discard tube, short draw, hemolysis, hemodilution, direct oral anticoagulants (FXa and direct thrombin inhibitors), antiplatelet drug (P2Y12 inhibitor). Only hemolysis and hemodilution above 30% were found to be interfering factors.
3. CFF: Potential interfering factors tested were absence of a discard tube, short draw, hemolysis, hemodilution, direct oral anticoagulants (FXa and direct thrombin inhibitors), and antiplatelet drug (P2Y12 inhibitor). Only hemodilution above 40% was found to be an interfering factor.

D. Platelet Mapping Assay

1. HKH: Potential interfering factors tested were absence of a discard tube, short draw, hemolysis, hemodilution, and epsilon amniocaproic acid. Only hemolysis and hemodilution levels above 40% were found to be interfering factors.
2. ActF: Potential interfering factors tested were short draw and hemodilution. Neither were found to be interfering factors.
3. ADP: Potential interfering factors tested were short draw, hemolysis, and hemodilution. Results show that short draws of 2.5 mL or less into a 4.0 mL tube and hemodilution at levels above 40% are interfering factors.
4. AA: Potential interfering factors tested were short draw, hemolysis, and hemodilution. Results should that short draws of 2.5 mL or less into a 4.0 mL tube and hemolysis are interfering factors.

XXI. TROUBLESHOOTING:

Preventative maintenance (PM) procedures should be conducted annually for optimal mechanical functioning of the analyzer and are performed by a trained Haemonetics representative. Documentation of those maintenance steps are included in the PM report.

A. The following guidelines must be maintained for optimal TEG performance:

1. Place the TEG on a flat surface.
2. Proper operation of the analyzer requires adequate airflow through the cooling fan at the rear of the device. Confirm that the fan is not obstructed by proximity to a wall or other equipment.

3. Isolate the instrument from all sources of heat.
4. The TEG must be operated at room temperature (10-32°C).

B. The following table lists the icons that may be displayed when operating the TEG. View the pop-up message on the touchscreen for more information.

Icon	Description
	The analyzer is connected to an external software application.
	The analyzer is being accessed by a remote user and is locked to prevent a local user from logging in. Contact POC staff if the instrument is needed for an emergent patient test.
	Data is being saved.
	Data is being collected.
	QC is overdue. Perform QC testing.
	Information
	Error
	Warning
	Critical error
	The patient test was completed. All parameters are finalized. The QC test passed.
	The patient test timed out before all parameters were finalized or an unrecoverable error occurred during the test. The QC test failed.
	The patient or QC test was stopped before all parameters were finalized.
	The test result is above the reference range.
	The test result is below the reference range.
	External QC is overdue. Run both levels of QC for the cartridge(s) indicated.

C. When an error occurs, the TEG displays a description of the error and instructions for correcting the issue. Follow the instructions exactly as displayed to avoid further errors.

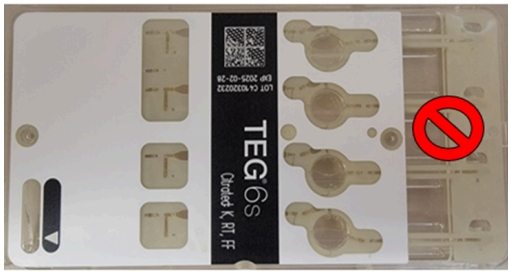
1. Note: If an error, warning, or critical message occurs during data collection, the data will not be saved.

D. The following table provides some examples of alerts. For error codes that are displayed on the analyzer but not included in the table, refer to the TEG 6s User Manual or contact TEG System Technical Support at 1-800-438-2834.

Error Code	Display Message	Probable Cause	Recommended Action
1005	Power-On-Self-Test optics error	During POST, one or more of the photodetectors are reading abnormally high or low, or it was not possible to calibrate the excitation LED(s) as desired.	Turn the power off and then back on to reboot the analyzer. If the problem persists, contact the site-specific POC department to contact TEG System Technical Support.
3007/ 3008	Sample initial fill level out of range for one or more channels.	Too little sample was delivered to the cartridge rings. This may indicate issues with optics, pressure, or cartridge.	Remove the cartridge and repeat the test using a new cartridge. If the problem persists, contact the site-specific POC department to contact TEG System Technical Support.
3054	Error reading barcode	Barcode cannot be read by analyzer	Remove the cartridge and rub the barcode with gauze or tissue to remove possible condensation. Wait a minute to allow the cartridge to warm and then repeat. If the problem persists, insert the cartridge in a different TEG or contact the site-specific POC department to contact TEG System Technical Support.
3069	Sample delivery timeout	Delivery of sample to test area did not complete in expected time.	Remove the cartridge and repeat the test using a new cartridge. Verify that the volume of blood sample is sufficient for the test. Fill up to or above the line marked on the side of the cartridge. If the problem persists, contact the site-specific POC department to contact TEG System Technical Support.

E. The door manifold clamps the cartridge in place when the light is not illuminated. Do not pull out the cartridge if the light is not blinking as it may break internal mechanical parts.

F. Do not handle the cartridge by the end containing the reaction cups. Only handle the cartridge by the area with the white label.



G. If the above items do not resolve the issue, contact the site-specific POC department for assistance.
    1. Dearborn: Call POC at 313-436-2367, 313-593-7970, or 313-982-5661.
    2. Royal Oak: Call Ancillary Testing at 248-898-8012.
    3. Troy: Call Decentralized Testing at 248-964-8009.

XXII. REFERENCES:

A. Point of Care Testing Approval Process
B. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.
C. TEG® 6s Hemostais System User Manual, Haemonetics Corporation, 125 Summer Street, Boston, MA 02110, 115191-US(AG) 4/2021 https://www.haemonetics.com/
D. TEG® 6s Hemostais System Citrated K, KH, RT, FF, Haemonetics Corporation, 125 Summer Street, Boston, MA 02110, 115873-US(AF) 4/2021 https://www.haemonetics.com/
E. TEG® 6s Hemostais System Citrated K, RT, FF, Haemonetics Corporation, 125 Summer Street, Boston, MA 02110, PN 121239-US(AE) 4/2021 https://www.haemonetics.com/
F. TEG® 6s Hemostais System PlateletMapping® ADP & AA, Haemonetics Corporation, 125 Summer Street, Boston, MA PN 115874-US(AG) 4/2021 https://www.haemonetics.com/
G. TEG® 6s Hemostais System Cartridge Reagent QC-Level 1, Haemonetics Corporation, 125 Summer Street, Boston, MA PN 128974-US(AC) 12/2021 https://www.haemonetics.com/
H. TEG® 6s Hemostais System Cartridge Reagent QC-Level 2, Haemonetics Corporation, 125 Summer Street, Boston, MA 4.40(AA) 4/2022 https://www.haemonetics.com/
I. TEG® 6s Hemostais System Validation Guide, Haemonetics Corporation, 125 Summer Street, Boston, MA 118597-US(AH) 12/2021 https://www.haemonetics.com/
J. Generic TEG® 6s Lab SOP, Haemonetics Corporation, 125 Summer Street, Boston, MA CL102741-US(AD) 1/2022 https://www.haemonetics.com/
K. TEG Manager® User and Site Administrator Guide, Haemonetics Corporation, 125 Summer Street, Boston, MA PN 128976-US(AC) 12/2021 https://www.haemonetics.com/
L. TEG 5000 System User Manual for Clinical Use Indications, Haemonetics Corporation, 125 Summer Street, Boston, MA 02110, 06-510-US(AF) 2/2017 https://www.haemonetics.com/

Attachments

POC TEG 6s Training and Competency Assessment.pdf

POC TEG 6s Training Guide.pdf

TEG 6s Instrument Comparison.pdf

TEG 6s New Lot Validation and Calibration Verification Log-Citrated Cartridges.pdf

TEG 6s New Lot Validation and Calibration Verification Log-Platelet Mapping Cartridges.pdf

TEG 6s QC and Maintenance Log.pdf

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	8/18/2023
CLIA Medical Director	Jeremy Powers: Chief, Pathology	8/18/2023
CLIA Medical Director	Vaishali Pansare: Chief, Pathology	8/17/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	8/17/2023
	Caitlin Schein: Staff Physician	8/15/2023
	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	8/15/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	8/11/2023
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Applicability

Dearborn, Royal Oak, Troy