Dignity Health
Central Coast Service Area Procedure

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| **Central Coast Service Area North:** |
| [x]  Santa Maria Campus,Marian Regional Medical Center | [ ] Arroyo Grande Campus,Marian Regional Medical Center | [ ] French Hospital Medical Center |
| **Central Coast Service Area South:** |
| [ ] St. John’s Pleasant Valley Hospital | [ ] St. John’s Regional Medical Center |  |

**SUBJECT**:TEG® 6s Hemostasis System for Citrated Sample Assays K, KH, RT, FF (Global Hemostasis [Purple box])

 **Lab Policy Number: 7500.CG.35a**

# Purpose:

The TEG® Analyzer and Citrated Multichannel Cartridge are used to test the hemostasis properties of citrated blood samples using different assays and reagents. The analyzer is useful as an additional tool to assess in near real time a patient’s hemostasis condition such as hemorrhage or thrombosis before, during, and following procedures to allow for a more targeted treatment. Evaluations are commonly performed for cardiovascular surgery and cardiology procedures.

# CLIA Complexity:

Moderate

# Clinical Utility:

The CK assay monitors the intrinsic pathway. Clotting Time, Speed of Clot Formation (K and Alpha angel) and Maximum Clot Strenth (MA) are measurements used to describe clotting characteristics.

The CRT assay monitors both the intrinsic and extrinsic pathways. Clotting characteristics are described only by the Maximum Clot Strength (MA). The CRT MA measurement is the same as the CK MA parameter but the final MA value is reached more rapidly using the CRT assay.

The CKH assay monitors the effects of Heparin. The CKH is used in conjunction with CK to compare Clotting times (R) to determine the influence of heparin.

The CFF assay monitors hemostasis by measuring Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV) when platelet contributions to clot strength are blocked.

# Principle:

The CK assay uses Kaolin to reduce running time by acting as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates clotting of the blood sample. Koalin combined with CaCl2 neutralizes sodium citrate in the blood.

The CRT assay (Rapid TEG) accelerates clotting by simultaneously activating the intrinsic and extrinsic pathways using high concentrations of Kaolin and Tissue Factor (TF). CaCl2 again is included to neutralize any sodium citrate in the blood.

The CKH (Kaolin and Heparinase) assay neutralizes heparin so developing coagulopathies can be monitored and are not masked by high levels of therapeutic heparin.

The CFF (Functional Fibrinogen) assay activates the extrinsic pathway using TF and inhibits platelet aggregation by inhibiting the GPIIb/IIIa receptor so the fibrinogen contribution to clot strength (MA) can be measured.

# CAlibration

The Teg 6s does not require routine calibration

# Materials: N/A

|  |  |  |
| --- | --- | --- |
| **Reagents / Media**Level 1 QC (stored 2-8ºC)Level 2 QC (stored 2-8ºC) | **Supplies / Materials**Citrated:K, KH, RT, FF cartridges (purple box) stored 2-8ºC in sealed foil pouches.  | **Equipment**TEG® 6STransfer pipettes |

# QUALITY CONROL

## Two levels of QC testing are required for each new shipment of cartridges or every 30 days to verify the performance of the system. Reconstituted QC material must be used within 2 hours.

### Remove two Citrated: K, RT, FF cartridge pouches from refrigerated storage and Level 1 and 2 control vials and two diluent water vials to sit at room temperature for approximately 10 minutes.

### After equilibrating to room temperature, tap the vials a few times to make sure lyophilized material is at the bottom of the vials.

### Remove stoppers and slowly pour the entire contents of the diluent water vials into each of the two control vials.

### Reinsert the stoppers and vigorously shake the control vials until fully reconstituted, and then incubate at room temperature for 5 minutes.

### Shake the control vials vigorously and let stand for 5 more minutes at room temperature.

### After the control vial is fully dissolved, tear open the cartridge pouch (Citrated: K, RT, FF [orange box] for Rapid TEG order)

### From *Home screen* on the analyzer, select **New QC**

### Insert the cartridge into the slot, as indicated on screen, with the barcode on the left side

### On the *Confirm Test* screen, touch **continue**

###  On the QC Level screen, touch **L1-Normal or L2-Abnormal** and then touch **Next**

### On the *Test Information screen*, enter information for the QC test (optional) and press **Next**

### Pipette the prepared QC sample into the cartridge sample port, filling up to or above the line marked on the cartridge

### Touch **Start Test.**

### When analyzer displays the “Remove cartridge” prompt, remove the used cartridge from the slot and immediately dispose of it.

### Compare the results against the reference ranges listed below. If all results fall within the ranges, touch **Pass.** If any result falls outside of reference ranges, touch **Fail**.

### Touch **Done** to return to the Home screen.

### If any of the results fall outside the reference ranges, repeat the test with a second cartridge from the same lot/shipment. If values still out, contact the manufacturer for further assistance.

### Repeat steps 6-17 for Level 2 control.

## Level 1-Normal QC sample with Citrated: K, KH, RT, FF results should fall within the following reference ranges:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Reagent & Normal QC | R (min) | K (min) | Angle (deg) | MA (mm) | FLEV (mg/dl) |
| CK | 4.6-13.1 | 0.8-4.1 | 58-81 | 55-73 |  |
| CRT |  |  |  | 55-77 |  |
| CKH | 3.6-8.6 |  |  |  |  |
| CFF |  |  |  | 55-73 | 1003-1333 |

## Level 2-Abnormal QC sample with Citrated: K, KH, RT, FF results should fall within the following reference ranges:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Reagent & Abnormal QC | R (min) | K (min) | Angle (deg) | MA (mm) | FLEV (mg/dl) |
| CK | 1.0-1.7 | 0.7-1.4 | 61-81 | 22-34 |  |
| CRT |  |  |  | 22-34 |  |
| CKH | 1.0-1.7 |  |  |  |  |
| CFF |  |  |  | 22-34 | 401-621 |

# Specimen Collection and preparation

## Use a 3.2% sodium citrate vacutainer as a discard tube, followed by two additional 3.2% sodium citrate tubes filled completely.

## After collection, gently invert tubes 5 times to mix. Do not send samples using Pneumatic Tube Transport System.

## Sample tubes should be used after 10 minute room temperature incubation and within 4 hours of draw.

## **NOTE:** Do not check for clots using a wooden stick. Always check for clots visually.

## Samples may be tested immediately in urgent situations.

# TEST procedure

## Remove one cartridge per specimen from the refrigerator.

## Tear open the pouch and remove the cartridge. Cartridges must be used within 2 hours after exposure to room temperature.

## From the *Home screen* on the TEG analyzer, touch **new test**

## Select patient ID and enter accession number then select **next**

## Follow prompt on screen by inserting the cartridge into the slot with barcode on left side.

## After the cartridge pretest has completed and the assay is confirmed, touch **next** (or **stop** if incorrect assay is selected)

## On the *Test Information screen*, enter information for the test (optional) and select **next**

## Using the included pipette, load blood into the cartridge sample port, filling up to or above the line indicated on the cartridge.

## Select next and the results will be displayed as they become available.

## *Remove cartridge* will be displayed when testing is completed. Remove and dispose of the used cartridge

# INTERPRETATION OF RESULTS

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Assay | Parameter | Ref Range (RR) | Parameter Result | Hemostatic Condition | Interpretation |
| CK | R (MIN) | 4.6-9.1 | Prolonged R value | Hypocoagulable | ↓ Coagulation factor activity and/or presence of heparin |
| Shortened R value | Hypercoagulable |  |
| CRT | MA(mm)(Rapid TEG) | 52-70 | Decreased MA | Hypocoagulable (low clot strength) | ↓ Fibrinogen or ↓ Platelet contribution |
| Increased MA | Hypercoagulable (high clot strength) | ↑Platelet contribution |
| CFF | MA(mm) | 15-32 | Decreased MA | Hypocoagulable | ↓ Fibrinogen |
| Increased MA | Hypercoagulable | ↑ Fibrinogen |

# ReSULTS

## Citrated K, KH, RT, FF [Purple box TEG order]. Print the results and enter in Cerner.

### CK TEST RESULTS: The R, K, Angle and MA results are measured and displayed at the conclusion of the test

### CRT TEST RESULTS: The MA result is measured and displayed at the conclusion of the test.

### CKH TEST RESULTS: Only the R result is needed and is displayed at the conclusion of the test.

### CFF TEST RESULTS: The MA result and the estimated Functional Fibrinogen Level (FLEV) are measured and displayed at the conclusion of test.

# Reporting results

## In MANUAL MODE of ACCESSION RESULT ENTRY, scan the patient barcode or manually enter the accession number. Enter results. If necessary, add a Result Comment or Result Note to document collection or processing problems and/or communications with nurses or physicians.

## Review results and select Perform. Re-enter accession number and select VERIFY when compete.

## Record QC results on log.

# Limitations of procedure

## See package insert for list of interfering Factors for each assay.

## TEG 6s analyzer results should be interpreted within the clinical context of the patient’s case. If the results are inconsistent with the patient’s condition, samples should be repeated or additional information should be used.

#  References

Mahla E., Suarez T., Bliden K., Rehak E., etal. Patelet Function Measurement-Based Strategy to Reduce Bleeding and Waiting Time in Clopidogrel-Treated Patients Undergoing Coronary Artery Bypass Graft Surgery: The Timing Based on Platelet Function Strategy to Reduce Clopidogrel-Associated Bleeding Related to CABG (TARGET-CABG) Study. Circ Cardiovasc Interv 2012: 5:261-269

TEG® 6s Package Insert. 2019.