Sutter Health
Sutter Roseville Medical Center

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Owner:	*Alex Alba: Spvr, Laboratory*
Policy Area:	*Lab - Coag*
References:	
Applicability:	*Sutter Roseville Medical Center*

Running Quality Control on the TEG 6s Hemostasis Analyzer

PURPOSE

This procedure describes how to run quality control on the TEG 6s hemostasis analyzer

POLICY

- The external QC is run upon receipt of a new shipment or new lot of test cartridges
- Citrated global hemostasis test cartridge uses the following external QC material: normal donor sample and abnormal QC
- Citrated global hemostasis with lysis (Trauma) test cartridge uses the following external QC material: normal donor sample, abnormal QC, and lysis QC
- Platelet Mapping test cartridge uses the following external QC material: normal donor and abnormal donor sample
- The appropriate corrective action is performed on any QC outlier and documented on the TEG 6s QC log
- The internal built-in QC validates that all components and functions of the analyzer-test cartridge combination are operating satisfactorily:
  - Power on self test- when analyzer is turned on, a system QC check is performed on all analyzer functions prior to loading of the test cartridge. Any failure will generate an error message and test will be invalidated.
  - Pre Test - when the test cartridge is inserted, a system QC check is performed to validate the ability of the analyzer to correctly identify the test cartridge and validate the integrity of the analyzer-cartridge interface. Any failure will generate an error message and prevent further system operation.
  - In Use - when the sample is added and test started, a system QC check is performed to monitor critical operational parameters throughout the duration of the test. If any parameter is out of range then test will be invalidated.

SCOPE

All CLS and MLT staff assigned to the Hematology/Coagulation department

PREPARATION AND STABILITY OF EXTERNAL QC

External QC	Test Cartridge	Storage and Stability	Preparation
Abnormal QC	• Citrated Global Hemostasis Test Cartridge • Citrated Global hemostasis with Lysis (Trauma) Test Cartridge	• Sealed vials are stored at 2-8°C • Use within 2 hrs of reconstitution	• Allow QC vial and diluent water vial to equilibrate at RT for 10 min • Tap the top of QC vial a few times to ensure lyophilized material is on the bottom of the QC vial • Remove seal and stopper of the QC vial, avoid the sharp metal edges • Slowly pour the contents of the diluent water into the QC vial and make sure no water drips out • Re-insert stopper in the QC vial • Hold stopper in place, vigorously shake the QC vial until fully reconstituted then let stand at RT for 5 min • Shake QC vial vigorously again and let stand at RT for 5 more min • Repeat until there is no undissolved material remaining in the QC vial
Abnormal and Lysis QC	• Citrated Global hemostasis with lysis (Trauma) Test Cartridge	• Sealed vials are stored at 2-8°C • Use within 2 hrs of reconstitution	• Allow abnormal QC vial, Lysis QC vial and diluent water vial to equilibriate at RT for 10 min • Tap the top of both QC vials a few times to ensure lyophilized material is on the bottom of each QC vial • Remove seal and stopper of the abnormal QC vial, avoid the sharp metal edges • Slowly pour the contents of the diluent water into the abnormal QC vial and make sure no water drips out • Re-insert stopper in the abnormal QC vial • Hold stopper in place, vigorously shake the abnormal QC vial until fully reconstituted then let stand at RT for 5 min • Shake abnormal QC vial vigorously again and let stand at RT for 5 more

			min • Repeat until there is no undissolved material remaining in the abnormal QC vial • Remove the seal and stopper of the Lysis control vial, avoid the sharp metal edges • Remove the stopper of the reconstituted abnormal control vial • Use the transfer pipette from the Citrated Trauma test kit and transfer the entire contents of the abnormal QC vial into the Lysis control vial • Replace the stopper on the Lysis control vial and invert the vial 5 times to mix the abnormal QC and Lysis control material. Repeat until there is no undissolved material remaining in the vial.
Normal Donor Sample	• Citrated Global Hemostasis Test Cartridge • Citrated Global hemostasis (Trauma) Test Cartridge • Platelet Mapping Test Cartridge	• Normal donor sample stored at RT in a horizontal position • Use after 10 minutes of collection at RT and within 4 hrs of collection for Citrated Global Multichannel and Citrated Trauma Test cartridges • Use after 30 minutes of collection at RT and within 2 hrs of collection for Platelet Mapping Test cartridge	• Refer to Haemonetics donor screening criteria for identification and selection of normal donor samples • Donors taking medications such as oral contraceptives, hormone replacement of any type, aspirin, ibuprofen, naproxen should be excluded • Refer to the TEG 6s specimen collection procedure to collect the appropriate blood tubes
Abnormal Donor sample	• Platelet Mapping Test Cartridge	• Abnormal donor sample stored at RT in a horizontal position • Use after 30 minutes of collection at RT and within 2 hrs of collection for Platelet Mapping Test cartridge	• Refer to Haemonetics donor screening criteria for identification and selection of normal donor samples • Refer to the TEG 6s specimen collection procedure to collect the appropriate blood tubes • To prepare aspirin spiked normal donor blood: ◦ Dissolve (1) 325 mg aspirin tablet in 200 ml saline

- add 160 ul of the ASA solution to the 4 ml heparinized blood tube
- Recap vial. Thoroughly and gently mix
- Incubate solution at RT for 30 min prior to testing

- To prepare Functional Fibrinogen rgt spiked normal donor blood:
  - Remove 3 vials of FF rgt from the refrigerator and allow to reach RT
  - tap the vials to ensure all contents are at the bottom of the vial
  - Remove seal and stopper on each vial, avoid sharp metal edges
  - Pipette 500 ul of whole blood into each of the FF vials
  - On each vial, replace the stopper then gently swirl and invert 5 times
  - Obtain a large sterile plastic container and pool the contents of the 3 vials
  - Gently swirl and invert 5 times prior to testing

PROCEDURE

Follow the procedure below to run QC on the TEG 6s

Step	Action
1.	Remove the test cartridge to use from refrigerated storage
2.	From the *Home* screen on the TEG analyzer, select **new qc**
3.	Tear open the cartridge pouch and when prompt, insert the cartridge into the slot as indicated with the bar code on the left side
4.	On the *Confirm Test* screen, touch **continue**
5.	After the cartridge pretest has completed and you have verified that the assay is what you intended to run, touch **next**
6.	On the **Test Information** screen: • Using the external QC barcodes located above the TEG 6s analyzers, scan the appropriate barcode of the QC that will be run (normal donor QC, abnormal QC, Lysis QC, abnormal donor QC)

	• Then touch next
7.	Pipette the prepared QC sample into the cartridge sample port, filling up to or above the line marked on the cartridge. Touch **next.** • The TEG analyzer starts the test • The results are displayed as they become available
8.	Touch **tracings** to view a graphic representation of the results • To cycle through superimposed, offset, and single-tracing views, touch **next tracing** until the desired view is displayed
9.	When the analyzer displays the "Remove cartridge" prompt, removed the used cartridge from the slot and immediately dispose of it in a biohazard container
10.	Print out and compare the QC results against the established QC ranges • Reagent performance is verified if the QC test results fall within the established QC ranges • Refer to section "Verifying External QC Results"
11.	Previously ran QC may be viewed from the *Home* screen by touching **stored qc** • Select the desired test, then touch results • 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, and an orange triangle indicates that the test was stopped early

VERIFYING EXTERNAL QC RESULTS

Step	Action
1.	Print the external QC results for the test cartridge in use
2.	Refer to the TEG 6s external QC reference range document to review the external QC results for the test cartridge in use and ensure values are within acceptable range

If	Then
QC results within acceptable range	• Initial the printouts • Place printout in the TEG 6s QC binder • Proceed to step 3
QC results outside acceptable range	• Repeat QC sample on test cartridge in use

If	Then
Repeat QC results within acceptable range	◦ Initial the printouts ◦ Place printouts in the TEG 6s QC binder ◦ Proceed to step 3
Repeat QC results outside acceptable range	◦ Notify Supervisor and contact Haemonetics tech support ◦ Do not use affected TEG

			6s analyzer for patient testing ◦ Initial the printouts ◦ Place printouts in the TEG 6s QC binder
3.	Proceed to patient testing when external QC results have been verified to be within acceptable ranges for test cartridges in use		

EXTERNAL QC REFERENCE RANGES

Abnormal & Lysis QC Citrated Global Hemostasis Test Cartridge	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)	LY30 (%)
CK	0.7 - 2.7	0.6 - 1.1	77 - 83	35 - 51	NA	82.0 - 98.0
CRT	NA	NA	NA	35 - 51	NA	NA
CKH	0.7 - 2.7	NA	NA	NA	NA	NA
CFF	NA	NA	NA	35 - 51	639 - 931	NA

Normal donor QC Citrated Global Hemostasis Test Cartridge	R (min)	K (min)	Angle (deg)	MA (mm)	FLEV (mg/dl)	LY30 (%)
CK	4.6 -9.1	0.8 - 2.1	63 - 78	52 - 69	NA	0.0 - 2.6
CRT	NA	NA	NA	52 - 70	NA	NA
CKH	4.3 - 8.3	NA	NA	NA	NA	NA
CFF	NA	NA	NA	15 - 32	278 - 581	NA

Platelet Mapping Test Cartridge	HKH-MA (mm)	ActF-MA (mm)	ADP-MA (mm)	ADP (%Inhib)	ADP(%agg)	AA-MA (mm)	AA (% inhib)	AA (% Agg)
Normal donor QC	53 - 68	2 - 19	45 -69	0 - 17	83 - 100	51 -71	0 - 11	89 - 100
Abnormal donor QC	<53	N/A	<45	>17%	<83%	<51	>11%	<89%

RELATED DOCUMENTS

- Running Specimens on the TEG 6s Hemostasis Analyzer
- Donor Screening Questions for Reference Range Study
- TEG 6s external control reference range document

REFERENCES

- Haemonetics TEG 6s User Manual

All revision dates: 5/17/2021, 1/4/2021

Attachments

Normal donor screening criteria.pdf
TEG 6s external QC ranges.xlsx

Approval Signatures

Step Description	Approver	Date
Laboratory Director	Lindsey Westerbeck: Dir, Lab	pending