#### Running QC on the TEG 5000 Hemostasis System

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| Background | This document describes how to run quality control samples on the TEG 5000 Hemostasis System |

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| Guidelines | * Level 1 and Level 2 quality control samples are run once every 24 hours on each channel on the TEG analyzer * Quality control samples are run at noon on the dayshift * Quality Control results must be within limits to perform patient testing |

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| QC Preparation | |  |  | | --- | --- | | Step | Action | | 1 | Remove control vial and corresponding diluent water from the refrigerator and allow to equilibrate at RT for approx 10 min. | | 2 | Tap the vial a few times to ensure control material is on the bottom of the vial. | | 3 | Remove seal and stopper from vial. | | 4 | Slowly pour 1 vial (1 ml) of the provided diluent water into the control vial. Ensure water does not drip out. | | 5 | Re insert the stopper into the control vial. | | 6 | Hold stopper in place and shake the vial vigorously until fully reconstituted then let stand for 5 min at RT | | 7 | After 5 min, shake vial vigorously again and let stand for additional 5 min at RT | | 8 | Repeat steps 1thru 7 for each control vial to prepare. | |

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| QC storageand Stability | * Reconstituted control samples are viable for 2 hrs at RT * Unopened vials are stable to expiration date when stored at 2-8°C |

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| Procedure A | Running Level 1 control sample on the TEG analyzer   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Step | Action | | | | | 1 | In the TAS screen, click the TEG button. | | | | | 2 | When the TEG screen displays, complete the channel section fields that correspond to the analyzer | | | | |  |  | | | | |  | **Field** | **Action** |  | | Channel | Prefilled with the channel number that corresponds to the column on the analyzer | | Sample Type | From the drop down list, select L1 –Level 1 control | | Patient name | From the drop down list, select the lot number for level 1 | | Sample description | Enter level 1 control’s HMO# | |  | | | | | 3 | Click on the first channel to select it.  Note: channel turns blue to indicated that it has been selected | | | | | 4 | In the TEG analyzer, load the clear cups and pins. | | | | | 5 | Pipette 20 uL of calcium chloride into each cup. | | | | | 6 | Pipette 340 uL of reconstituted Level 1 control into the cup in the first channel | | | | | 7 | Immediately and carefully raise the carriers until they are flush with the bottom of each column.  **Note: Do not push up the carrier too quickly to avoid displacing the QC material in the cup by the pin** | | | | | 8 | Move the lever to the Test position. | | | | | 9 | In the TEG screen, press F10 or click the Start button  Note: first channel turns green to indicate that it is active and second channel turns blue to indicate that is has been selected | | | | | 10 | Repeat steps 5 thru 8 steps to run controls samples on channels 2 thru 4. | | | | | 11 | To view results, click Done to return to the TAS Main screen | | | | | 12 | Allow the control samples to run until the MA parameter is resulted and defined (no asterisks appear next to the value). | | | | |

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| Procedure A, Cont | |  |  | | --- | --- | | Step | Action | | 13 | From the TAS Main screen or TEG screen, select the first channel to stop and click the Stop button or F11, when QC testing is complete. | | 14 | Click Yes in the confirmation message that displays on the screen.  Note: channel turns white, indicating the sample is terminated | | 15 | Repeat steps 13 and 14 to stop the next channels. | | 16 | On the TEG analyzer, move the levers on the channels from to Test to Load position.  **Note: Always terminate the control samples before moving the lever to the Load position** | | 17 | Eject the control samples and dispose the samples properly  Note: Do not exert extreme pressure on the lever. If pin does not eject, press down the lever and remove pin by hand | |

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| Procedure B | Running level 2 control sample on the TEG analyzer   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Step | Action | | | | | 1 | In the TAS screen, click the TEG button. | | | | | 2 | When the TEG screen displays, complete the channel section fields that correspond to the analyzer | | | | |  |  | | | | |  | **Field** | **Action** |  | | Channel | Prefilled with the channel number that corresponds to the column on the analyzer | | Sample Type | From the drop down list, select L2 –Level 2 control | | Patient name | From the drop down list, select the lot number for level 2 | | Sample description | Enter level 2 control’s HMO# | |  | | | | | 3 | Click on the first channel to select it.  Note: channel turns blue to indicated that it has been selected | | | | |

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| Procedure B, Cont | |  |  | | --- | --- | | Step | Action | | 4 | In the TEG analyzer, load the clear cups and pins. | | 5 | Pipette 20 uL of calcium chloride into each cup. | | 6 | Pipette 340 uL of reconstituted Level 2 control into the cup in the first channel | | 7 | Immediately and carefully raise the carriers until they are flush with the bottom of each column.  **Note: Do not push up the carrier too quickly to avoid displacing the QC material in the cup by the pin** | | 8 | Move the lever to the Test position. | | 9 | In the TEG screen, press F10 or click the Start button  Note: first channel turns green to indicate that it is active and second channel turns blue to indicate that is has been selected | | 10 | Repeat steps 5 thru 8 steps to run controls samples on channels 2 thru 4. | | 11 | To view results, click Done to return to the TAS Main screen | | 12 | Allow the control samples to run until the MA parameter is resulted and defined ( no asterisks appear next to the value). | | 13 | From the TAS Main screen or TEG screen, select the first channel to stop and click the Stop button or F11, when QC testing is complete. | | 14 | Click Yes in the confirmation message that displays on the screen.  Note: channel turns white, indicating the sample is terminated | | 15 | Repeat steps 13 and 14 to stop the next channels. | | 16 | On the TEG analyzer, move the levers on the channels from to Test to Load position.  **Note: Always terminate the control samples before moving the lever to the Load position** | | 17 | Eject the control samples and dispose the samples properly  Note: Do not exert extreme pressure on the lever. If pin does not eject, press down the lever and remove pin by hand | |

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| Verifying Control Sample Results | |  |  |  |  |  | | --- | --- | --- | --- | --- | | Step | Action | | | | | 1 | Print the QC results for levels 1 and 2 for each channel | | | | | 2 | Review level 1 and level 2 QC results for each channel and ensure that the values for R,K, Angle, and MA are within acceptable range | | | | |  |  | | | | |  | **If** | **Then** |  | | QC within acceptable range | * Staple all QC printouts together * Place initials on the printouts * Place in the QC file for the appropriate date * Proceed to step 3 | | QC outside acceptable range | * Repeat the control sample on the affected channel * Document corrective action on the QC printout * Proceed to step 3 if repeat results are within limits * If repeat results not within limits, call tech support * Staple all QC printouts together * Place initials on the printouts * Place in the QC file for the appropriate date | |  | | | | | 3 | Proceed to patient testing when QC results for levels 1 and 2 have been verified to be within acceptable ranges | | | | |

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| Related Documents | * Loading cups and pins on the TEG 5000 Hemostasis System * TEG 5000 User Manual |

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