#### 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  |

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| 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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Running QC on the TEG 5000 Hemostasis System, Continued

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| Procedure A | Running Level 1 control sample on the TEG analyzer

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| 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 |
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|  | **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# |
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| 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 buttonNote: 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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Running QC on the TEG 5000 Hemostasis System, Continued

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| Procedure A, Cont |

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| 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 properlyNote: 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

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| 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 |
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|  | **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# |
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| 3 | Click on the first channel to select it.Note: channel turns blue to indicated that it has been selected |

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Running QC on the TEG 5000 Hemostasis System, Continued

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| Procedure B, Cont |

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| 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 buttonNote: 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 properlyNote: 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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Running QC on the TEG 5000 Hemostasis System, Continued

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| Verifying Control Sample Results |

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| 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  |
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|  | **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
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| 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
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| 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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Running QC on the TEG 5000 Hemostasis System, Continued

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