#### Running and Evaluating Quality Control on the Sysmex XN-3100 Hematology Analyzer

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| Background | This procedure describes how to run and evaluate commercial blood controls (XN CHECK) on the Sysmex XN analyzer |

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| Policy | * Scheduled QC runs will be performed using two of the three XN Check control levels as follows:
* 0700 +/- 15 min Level 1 and 3
* 1500 +/- 15 min Level 2 and 3
* 2300 +/- 15 min Level 1 and 2
* All three levels of control must be run after calibration, major maintenance or service, or software change.
* QC means are established for each new control lot by collection of at least 10 data points per control level over 5 days. The calculated mean should be within the expected ranges listed on the Sysmex control lot insert. Evaluation period may be shortened with supervisor approval in extreme circumstances (i.e. shipping delays, damage to control material, etc.)
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| Procedural Notes | * Controls must be run at the scheduled time ± 15 minutes.
* Sysmex Evidence-Based Control Limits: The range limit percentages were developed using Six Sigma methods, which uses evidence such as, parameter-specific performance goals, bias, and CV.
* Acceptable XN CHECK control values for a given lot # are located by clicking on the QC file icon and selecting the current control level. The LJ charts show historic QC data and the radar graphs display data from the last QC run.
* CAP requirement for new reagent lot and/or new shipment verification is met by running of controls within 8 hours of any reagent change
* CAP requirement for annual verification of accuracy and reproducibility of analytic instruments with integral automatic pipettors is met by routine analysis of quality control material
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| Supplies | * Sysmex XN-CHECK Hematology Controls (Levels 1,2 and 3)
* Unopened vials of XN-CHECK when stored at 2-8oC is stable until manufacturer's expiration date.
* Open vials and vials which have been sampled by cap piercing are stable for 7 days if stored at 2-8oC after being re-capped.
* Write new expiration date and tech code on vial.
* Return vial(s) to refrigeration after use within 30 minutes.
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| Procedure | Follow the steps below to run the controls

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| Step | Action |
| 1 | Remove appropriate control levels from refrigerator and check expiration date. Do not use expired controls |
| 2 | Allow controls to warm to room temperature for 15 minutes before use/prior to mixing. |
| 3 | Hold the vial vertically and roll each vial between the palms of the hands for 15-20 sec |
| 4 | * Continue to mix by holding the vials by the ends between the thumb and finger, rapidly inverting the vial 20 times end over end using a very quick turning motion of the wrist
* Analyzer immediately after mixing
* Do not mix mechanically or by vortex
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| 5 | Ensure the analyzer and sampler are in the Ready state |
| 6 | * On the individual XN unit, place control vials in a rack and run in the automated closed mode or
* On the individual XN unit, run each control vial in the open manual mode
* Refer to the procedure Running whole blood specimens on the XN 3100 hematology analyzer using the closed and open mode
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| 7 | Results will be plotted on the LJ chart as well as the Radar chart for review. **CLS must review control results before proceeding with patient testing, refer to Reviewing Control Results section** |
| 8 | Once QC has been reviewed and accepted, place control vials back in refrigerated storage |

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| Reviewing Control Results | Follow the steps below to review the controls

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| Step | Action |
| 1 | After controls are analyzed, from the main menu, select QC Files. On each module (i.e. XN 1 and XN 2), use the tabs near the bottom of the screen to select the analyzer (ex. XN 1-R, XN 1-L). |
| 2 | * Review results for each control level by clicking on each QC level for each analyzer. The radar graph will display
* Make sure the radar graph displays current QC run date/time
* Double click to see the LJ charts or select QC chart.
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| 3 | * Verify test parameters on each control are within acceptable limits
* Document tech code on the analyzer’s maintenance log once review is complete
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|  | **If** | **Then** |  |
| Test parameters are within acceptable limits for each control | * Controls acceptable
* OK to proceed with patient testing
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| One or more test parameters exceeds acceptable limits on one or more controls. | * Controls not acceptable
* Do Not proceed with patient testing on that analyzer. Proceed to section *Resolving Unacceptable QC Results*
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| Resolving unacceptable control results | Follow the steps below to resolve unacceptable control results

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| Step | Action |
| 1 | Verify expiration of controls and reagents. Replace any controls and/or reagents that are expired |
| 2 | Verify required analyzer maintenance has been done. If not, perform needed maintenance |

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| Resolving unacceptable control results, cont |

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| Step | Action |
| 3 | For each unacceptable control, repeat control using same vial (if not expired) |
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|  | **If** | **Then** |  |
| Repeat control is acceptable | * No further action needed. Proceed with patient testing
* Document corrective action on QC Corrective Action log
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| Repeat control is not acceptable | * Proceed to Step 4.
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| 4 | Repeat control level using a new control vial (if not already done) |
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|  | **If** | **Then** |  |
| Repeat control using new vial is acceptable | * No further action needed. Proceed with patient testing
* Document corrective action on QC Corrective Action log
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| Repeat using new vial control is not acceptable | * Proceed to Step 5
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| 5 | Contact Sysmex Technical Service and/or refer to the troubleshooting section of the XN-3100 Instructions for Use manual for additional corrective action instructions |
| 6 | * Once issue resolved, repeat all three levels of controls. Document corrective action on Corrective Action log.
* Do Not run patient samples until all controls are within acceptable limits for each test parameter QC
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Running and Evaluating Quality Control on the Sysmex XN-3100 Hematology Analyzer, Continued

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| Resolving unacceptable control results, cont |

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| Step | Action |
| 7 | When necessary, conduct a "lookback" to verify patient results obtained in an analytically unacceptable test run (i.e. the time period between the failed QC run, back to the most recent preceding successful QC run):* Re-run every 10th patient sample until you are able to pinpoint when the problem arose. There is no need to go past the last successful QC run.
* Then re-run all patients tested on the affected analyzer to the time of the QC failure to the pinpointed failure or last successful QC run.
* If samples are not available to re-run, refer to Supervisor for further evaluation.

Consult with Supervisor or Technical Coordinator to correct clinically significant result difference for the test parameter(s) that was out of control. |
| 8 | If needed, Consult with Supervisor to correct clinically significant result difference for the test parameter(s) that was out of control |

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| Procedural Notes | * PLT and PLT related parameter results such as the MPV, IPF that recover outside the expected ranges may indicate inadequate mixing of control material
* Increased % CV may also indicate inadequate mixing of control material
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| Related Documents | * Form A: Sysmex XN QC corrective action log
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| References | * Sysmex XN Operator’s manual, March 2017
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