#### Calibration and Calibration Verification of the Sysmex XN-3100 Hematology Analyzer

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| **Background** | This procedure outlines the calibration / calibration verification process for the Sysmex XN-3100 |

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| **Policy** | * Instrument calibration or calibration verification
* At least every six (6) months.
* Following major maintenance, service and/or replacement of critical parts
* Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting
* When calibration verification fails
* When advised by Sysmex Technical Service
* Calibration is performed initially and verified by the Sysmex Field Service Representative or CLS with remote assistance from Sysmex Technical Support
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| **Supplies** | * XN CAL: Used for calibration of the analyzer for:
* WBC, RBC, HGB, HCT, PLT, AND RET
* XN CAL PF: Used for calibration or the analyzer for:
* PLT-F
* Calibrators are stable until the manufacturer's expiration date. Store at 2-8oC. ***Open calibrator stability is 4*** ***hours.***
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| **Procedure** | Follow the steps below to perform calibration or calibration verification.

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| Step | Action |
| 1 | Allow calibration materials to warm to room temperature for at least 15 minutes prior to use |
| 2 | Verify adequate reagents are on board analyzer.* If a reagent runs out during the calibration process, the calibration stops. If this occurs:
* Cancel the calibration
* Replace the needed reagent
* Restart calibration from the beginning
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| 3 | Perform calibration according to instructions of the Sysmex XN 3100 Instructions for Use manual |
| 4 | Following calibration, run QC using the three XN CHECK control levels. Refer to *Running and Evaluating QC on the Sysmex-3100 Hematology Analyzer*. |

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Calibration and Calibration Verification of the Sysmex XN-3100 Hematology Analyzer, Continued

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| Related documents | * Running and Evaluating controls on the Sysmex XN 3100 Hematology analyzer
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| References | Sysmex XN 3100 Operator’s manual, March 2017Sysmex XN-Series Automated Hematology Systems, Flagging Interpretation Guide, March 2018 |

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