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| **Laboratory Department Standard Operating Procedure: Sysmex XN Quality Control** | |
| **Document Identification:** 09-SMHC-12783 | |
| **Laboratory Section:** Hematology | |
| **Document Owner:** Jessie Hanson | **Document Creator:** Jessie Hanson |
| **Implementation Date:** 12/05/2018 | **Date of Review:** 12/05/2018 |
| **Approved by:** Constance Threlkeld | **Approval Date:** 12/15/2018 |

**Purpose:**

To standardize the performance of quality control procedures of the hematology department automated instruments and to ensure compliance with facility quality-assurance programs and regulatory agency requirements.

**Discussion:**

Maintaining laboratory instruments in control is a vital aspect of high-quality patient care. Without quality controls, there is no way to ensure or document that the patient results reported are indeed accurate. SCL is committed to the highest level of patient care as demonstrated through our adherence to quality control testing protocols.

Quality control testing yields data on two aspects of instrument performance.

1. Daily performance--quality control results track instrument performance throughout the operational day.
2. Cumulative performance--quality control results track instrument performance over time.

Both of these groups (daily and cumulative performance data) are comprised of two types of analyzer data

1. Point-in-Time Control--results compared to known assay values for control materials in order to confirm instrument accuracy and reliability at any individual point in time.
2. Moving Average-- grouped patient results compared to each other in order to track changes in instrument performance over time.

**Scope:**

This Standard Operating Procedure applies to all technologists who are trained and competent to perform quality control.

**Definitions:**

* Patient specimen: sample of whole blood collected from a patient
* Control specimen or QC specimen or QC materials: known-value materials used to establish instrument accuracy and performance
* QC--”quality control”; refers to the performance of quality-control testing

**Policy: Quality Control**

* Three levels of stabilized quality controls supplied from the Sysmex manufacturer are to be performed for every 24 hours of patient-specimen testing. After any change that may affect results, QC must be run before any patient testing. Such changes include any change of analytically-involved reagents, maintenance of the instrument, change of an instrument component, or operational software changes.
* When a QC results falls outside acceptable ranges (as defined by the manufacturer’s publications), analysis and corrective action must be performed to return QC values to acceptable levels. All control levels must fall within these acceptable ranges before any patient values are reported. All corrective action must be documented in the “Instrument Event” (see document 09-SMHC-17843) and “Corrective Action” (see document 09-SMHC-89457) logs.
* QC specimens must be run in the same manner as patient specimens. This ensures that all aspects of testing are controlled.
* When a new lot of control specimens is begun, mean values and acceptable limits must be verified by running at least ten repetitions of each level over a minimum of five days.
* QC results are stored in the “QC” file of the “Data” screen on the instrument. The hematology department technologist will review them on every shift. The hematology technical specialist will review them every month or more frequently, if indicated by any trend over time, sudden shift from the mean, or other consistent bias that would require corrective action.

**Commercial QC Materials:**

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| **Sysmex XE Hematology Controls** |
| Sysmex XE is a whole-blood commercial control material for use with the Sysmex XN instrument. Three levels of assayed whole blood quality control are used to confirm and monitor complete blood counts, white blood cell differentials, reticulocytes, and nucleated red blood cells.  **Stability:** QC specimens are stable for seven days after opening when refrigerated at 2-6 degrees Celsius. Unopened QC specimens are stable until the manufacturer’s printed expiration date, when stored at 2-6 degrees Celsius.  **Storage:** Store capped QC specimens at 2-6 degrees Celsius. Heat or cold beyond these parameters can damage the specimen’s integrity without visible changes. If the mean of the QC specimen is not within acceptable assay ranges, contamination or deterioration is suspected. |

**QC Frequency:**

Commercial quality controls are run every 8 hours.

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| **Shift** | **Sysmex XE Hematology Controls** |
| 1st Shift  0700 | Level 1  Level 3 |
| 2nd Shift  1500 | Level 2  Level 3 |
| 3rd Shift  2300 | Level 1  Level 2 |

**Running QC:**

Commercial quality controls must be run on both instruments in the hematology department.

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| **Step** | **Action** |
| **1** | Remove QC materials from refrigerator and warm to room temperature for 15 minutes. |
| **2** | Mix controls by gentle, manual inversion until well-mixed. Do NOT use a mechanical rocker. |
| **3** | Place QC materials in a sample rack with manufacturer barcodes facing forward, visible to the instrument scanner. |
| **4** | Place sample rack in the instrument intake platform. |
| **5** | Make sure the instrument is in “Ready” mode, as shown in the primary display screen.   * Green LED should be lit * Screens should display “Auto Mode.” |
| **6** | Press “Run” on the instrument control panel. |

**Reviewing Quality Control Values:**

After running the assigned levels of commercial QC materials, the hematology department technologist must review the values and make sure they are acceptable.

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| **Step** | **Action** |
| **1** | Click on the “QC” file in the “Data” screen of the instrument. |
| **2** | Choose the desired control file from the “Level” dropdown menu. Make sure the correct file is chosen by referencing the time and date of the run. The instrument will render a Levy-Jennings chart of the last two weeks of QC values. |
| **3** | Review results on the Levy-Jennings for all indices within a complete blood count, including white blood cell, reticulocyte, and nucleated red blood cell counts. Any values outside 2 standard deviations from the mean will flag as a red “x” within the L-J chart. |
| **4** | If any values flag with red “x’s,” rerun that level of control. If values are still outside acceptable limits (2 standard deviations), troubleshoot the problem using guidelines found in document 09-SMHC-12654. Do not run any patient specimens until all levels of control are within acceptable limits. |
| **5** | After QC is reviewed and determined to be acceptable, resume patient testing and resulting. |

**Additional Quality Control: Blind Duplicate Whole Blood**

After replacing an analytically-involved reagent, a blind duplicate patient sample is run as a pre- and post-change quality monitor.

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| **Step** | **Action** |
| **1** | Locate a recently-resulted patient specimen with normal values for a complete blood count. (If a patient specimen with normal values is not available, choose one with higher-than-normal values.) |
| **2** | Load the patient specimen into the specimen rack with the barcode facing back, hidden from the instrument scanner. |
| **3** | When the “Unidentified Specimen” crosses into the software interface, manually change the specimen identification number to “B-XXXX” (with XXXX being the original patient specimen number.) This will prompt the software to display the current and previous results on the screen for comparison. |
| **4** | Compare all current and previous results and make sure that they fall within 2 standard deviations of each other. |
| **5** | If results are not within 2 standard deviations of each other, repeat steps 2-4. If results still do not fall within 2 standard deviations, troubleshoot the instrument per guidelines found in document 09-SMHC-12654. |
| **6** | If the laboratory information system is down, standard deviation values can be found in document 09-SMHC-98765. |
| **7** | After the blind duplicate control is found to be acceptable, resume patient testing and resulting. |

**Conclusion:**

Quality controls are a crucial piece of laboratory safety, accuracy, and quality. [This facility] adheres to the highest standards of integrity and safety in our policies and practices, including quality controls.

**Related Procedures**

* Troubleshooting the Sysmex XN Hematology Instrument, 09-SMHC-12654.
* Standard Deviation Values for the Sysmex XN Hematology Instrument, 09-SMHC-98765
* Hematology Instrument Event Log, 09-SMHC-17843
* Hematology Instrument Corrective Action Log, 09-SMHC-89457

**References:**

* Sysmex XE Control System for X-series Instruments, Package Insert 348722, revised April, 2012
* Sysmex XN Automated Hematology Instrument CLN/SNHE Procedure Complete Blood Count of EDTA Whole Blood, Mundell, IL JKT-96-34402, revised May 2016
* Sysmex XN Operator’s Guide, JKT-76-93345, revised August 2015
* Sysmex XN Operator’s Quick Reference Guide, JT-34-34872, revised August 2015
* Sysmex XN Instructions for Use, Sysmex Corporation, Marseilles, France, revised August 2015
* Sysmex XN Software Guide, Sysmex Corporation, Marseilles, France, revised August 2015.