# STEM CELL LABORATORY (STCL)

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**DOCUMENT TITLE:**

Sysmex XN-450 Hematology Analyzer Precision and Calibration Checks

**DOCUMENT NOTES:**

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# STCL-EQUIP-023 JA5
# SYSMEX XN 450 HEMATOLOGY ANALYZER PRECISION AND CALIBRATION CHECKS

## Option One – BeyondCare Quality Monitor for Hematology (BCQM$^h$)

The BCQM$^h$ system is an advanced accuracy and precision verification system that verifies calibration each time two levels of QC are analyzed, and the results fall within algorithm specification guidelines developed for the BCQM$^h$ program. BCQM$^h$ program requires a minimum of two QC levels analyzed every 24 hours which means calibration verification will be verified every 24 hours; more often if QC frequency occurs 2-3 times daily. This analysis is performed for all parameters contained in the QC product.

When at least two different levels of control recover within BCQM$^h$ specifications, calibration verification passes. A green analyzer status is displayed on the dashboard page and the Summary report will show a "P" (pass) for that QC run.

The Continuous Calibration Verification (CCV) Certificate provides an on-demand report for documenting accuracy and precision of the test method and can be generated whenever documentation is needed.

When BCQM$^h$ identifies changes in accuracy or precision that cannot be resolved through normal analyzer maintenance, the analyzer status in the Dashboard view is Red with the Summary view red with "F" for failing calibration verification specifications. When required, calibration will be completed by Sysmex SE following the Sysmex sponsored Managed Calibration program as defined by the service contract. The BCQM$^h$ Calibration History tab also documents calibration events.

## Option Two – Managed Calibration

Sysmex-sponsored calibration/precision events defined by the analyzer and service contract are referred to as *Managed Calibration*. Calibration and/or calibration verification procedures are performed by a Sysmex SE on-site. The following items are completed by the Sysmex representative during the calibration verification process:

- Documentation and review of analyzer service history.
- Documentation and review of QC testing results.
- Documentation and review of historical Sysmex ***Insight***™ reports.
- Analyzing the Sysmex calibrator according to the manufacturer's recommendations to verify precision and calibration (accuracy) of the analyzer.
- Documentation of calibration verification results and generation of a calibration verification certificate for laboratory records.

## Option Three

Precision and Calibration may be performed by the operator. The operator may calibrate the following parameters using XN CAL calibrator: WBC, RBC, HGB, HCT, and PLT.

## 1. PRECISION CHECK

1.1. Perform routine daily and weekly maintenance on the instrument and perform a background count to ensure counts are within acceptable limits.

1.2. Verify that there is sufficient volume of all reagents. Precision and Calibration procedures will be aborted if the Sysmex XN 450 runs out of reagent.

1.3. Obtain a sample of fresh normal whole blood. Do not use commercial controls or calibrators for precision. The blood donor specimen should:

1.3.1. Be free from medication, and interfering substances such as lipemia, icterus, platelet clumps, hemolysis, etc.

1.3.2. Have morphologically and numerically normal CBC.

1.3.3. Be drawn in EDTA anticoagulant tube using proper collection technique.

1.3.4. Be a minimum of 2.5 mL sample.

1.4. On the main unit, check the Status indicator LED. Confirm the LED is green, indicating the analyzer is **Ready**.

1.5. Select the Analyzer menu button on the control menu.

1.6. Select [Calibration]- [Precision Check]

1.7. Mix the vial containing the sample- 10 end-over-end inversions confirming cell button is dispersed.

1.8. Place the well-mixed sample tube in the tube holder.

1.9. Press the start switch on the analyzer.

1.10. Repeat mixing and analysis (total of 11 times).

1.11. The results are displayed in the [Precision Check] analysis dialog box.

1.12. If the analysis results do not satisfy conditions for normal results or if results are outside acceptable limits, the test numbers of the tests that must be repeated are displayed. Select and redo the manual analysis.

1.13. When all analysis results satisfy the conditions, select [OK] in the dialog box. Select [YES] to record passing precision results in the precision check history.

## 2. CALIBRATION XN CAL

2.1. Prepare the Sysmex XN CAL calibrator according to the product insert.

Store vials in the upright position, at 2-8˚ C. Do not freeze or expose vials to excessive heat. Unopened and properly stored, XN CAL is stable until the expiration date reflected on the vial. **Open vial stability is 4 hours**

2.2. On the main unit, check the Status indicator LED. Confirm the LED is green, indicating the analyzer is **Ready**.

2.3. Select the Analyzer menu button on the control menu.

2.4. Select [Calibration]- [Calibrator Calibration]

2.5. Mix the vial – 10 end-over-end inversions confirming the cell button is dispersed.

2.6. Place the vial in the sample tube holder.

2.7. Press the Start switch on the analyzer.

2.8. Repeat mixing and analysis (total of 11 times).

2.9. The results are displayed in the [Calibrator Calibration] analysis dialog box.

2.10. If the analysis results do not satisfy conditions for normal results, or if results are outside acceptable limits, the test numbers of the tests that must be repeated are displayed. Select and redo the manual analysis.

2.11. When all analysis results satisfy the conditions, select [Calibration] in the dialog box.

2.12. Select [OK] to display results in the [Calibrator Calibration] execution dialog box.

2.13. Select the check box to include the calibration parameter in the calibration exercise, clear the check box to exclude the parameter in the calibration exercise. If a parameter meets all the following criteria, the check box will automatically be selected.

a. 80% ≤ New Rate ≤ 120%

b. New Rate- Current Rate < + 5

c. Range Value ≤ Max Range

d. Acceptable Limit < Delta Percent < Service Limit

If a parameter meets all the conditions and the Delta Percent is less than the Acceptable Limit, it is excluded from the calibration as there is no need for calibration.

If a parameter does not meet all the conditions and the Delta Percent is greater than the Acceptable Limit, the calibration cannot be performed. Calibration is performed with the parameter excluded. Selecting the check box enables you to manually enter a value in [New Rate (%)]. A range of 80% to 120% may be entered.

2.14. Select [OK] to update the compensation rates. The calibration process is logged in the calibrator calibration history.

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## Signature Manifest

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### STCL-EQUIP-023 JA5 Sysmex XN-450 Hematology Analyzer Precision and Calibration Checks

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