

Sysmex XN 550 Calibration & Precision

Policy

Initial calibration is performed during installation by the Sysmex Service Engineer. **The Instructions for Use for the XN-L Series of analyzers states that calibration is to be performed ONLY when indicated by a change in QC status, or after a major hardware component change.** The calibration of Sysmex hematology analyzers does not expire. It is not recommended to make time-based adjustments to the analyzer calibration as this can decrease the quality of the results over time.

Calibration verification occurs when materials of known concentration are tested in the same manner as patient specimens to assure that the test system is accurately measuring samples throughout the reportable range. If results from the test system match the calibrator or standard's assayed results, calibration is verified.

Historically, a calibrator has been used on a semi-annual basis as a "check" of daily QC procedures.

The CLIA requirement states that calibration verification requirements are met when:

1. The lab follows manufacturer's instruction for instrument operation
2. The lab tests two levels of control materials each day, whereby the control results meet the laboratory's criteria of acceptability.

BeyondCareSM Quality Monitor for Hematology (BCQM_h) is the peer group quality assurance and calibration verification program. It is utilized to monitor analyzer calibration status and performance and do not require on-site calibration verification after the initial installation. Instead, the BCQM_h program is used for continuous calibration verification.

The BCQM_h program provides a calibration verification system that may detect issues earlier than with traditional quality control methods. Because the XN-L CHECK™ controls are cleared by the FDA for use as control and calibration verification materials, calibration status is confirmed every time the controls are analyzed. These control materials are traceable to the same international conventional reference measurement procedures as XN CAL™ hematology calibrators.

When an issue is identified that cannot be resolved via online troubleshooting or remote assistance BCQM_h automatically dispatches a service representative to perform on-site troubleshooting and, if required, calibration. Once the calibration is completed, BCQM_h resumes monitoring the analyzer.

Safety

Refer to the safety manual for general safety requirements.

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Reagents XN CHECK and XN-L CHECK are intended for use in continuous calibration verification of the Sysmex XN-Series and Sysmex XN-L Series analyzers

Calibrators

XN CAL™: for use in calibrating the analyzer for WBC, RBC, HGB, HCT, and PLT

XN CAL Storage

- a) Store the calibrator in a dark refrigerator at 2-8°C

XN CAL Stability

Unopened and properly stored, XN CAL is stable until the expiration date printed on the unopened

Procedure

The most common processes for Precision and Calibration of the Sysmex analyzer is the utilization of Sysmex sponsored calibration/precision events defined by the analyzer service contract. Calibration verification procedures may be done by a Sysmex SE on-site or remotely through the Sysmex Network Communications System (SNCS™) with the Sysmex Calibration Specialist. 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.

The following are the on-site calibration steps:

A. Precision Check

Step	Action
1	Perform routine maintenance on the analyzer and perform a background count to ensure counts are within acceptable limits.
2	Verify that there is sufficient volume of all reagents. Precision and Calibration procedures will be aborted if the XN-550 runs out of reagent.
3	Obtain a sample of fresh normal whole blood. Do not use commercial controls or calibrators for precision. The blood donor specimen should: <ul style="list-style-type: none">a) Be from a healthy person who is not taking any medication

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	<ul style="list-style-type: none"> b) Have morphologically and numerically normal CBC. c) Be drawn in a potassium EDTA anticoagulant tube using proper collection technique. d) Have a minimum of 2.5 mL of sample.
4	On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready .
5	Select the Analyzer menu button on the control menu.
6	Select [Calibration] – [Precision Check]
7	Mix the vial containing the sample – 10 end-over-end inversions confirming cell button is dispersed
8	Place the vial in the sample tube holder
9	Press the start switch on the analyzer.
10	Repeat mixing and analysis (total of 11 times).
11	<p>The results are displayed in the [Precision Check] analysis dialog box.</p> <ul style="list-style-type: none"> a) 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.
12	When all analysis results satisfy the conditions, select [OK] in the dialog box.
13	Select [Yes] to record passing precision results in the precision check history.

NOTE: If an error occurs during analysis and the analysis can no longer continue, stop precision check. Once the error is cleared, redo the manual analysis.

B. Calibration – XN CAL

Step	Action
1	On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready .
2	Select the Analyzer menu button on the control menu
3	Select [Calibration] – [Calibrator Calibration]
4	Mix the vial containing the calibrator according to package insert
5	Open the Sampler Cover (Manual Unit).
6	Place the vial in the sample tube holder

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7	Press the start switch on the analyzer.
8	Repeat mixing and analysis (total of 11 times).
9	The results are displayed in the [Calibrator Calibration] analysis dialog box.
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.
11	When all analysis results satisfy the conditions, select [Calibration] in the dialog box.
12	Select [OK] to display results in the [Calibrator Calibration] execution dialog box.
13	<p>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:</p> <ul style="list-style-type: none"> a. $80\% \leq \text{New Rate} \leq 120\%$ b. $\text{New Rate} - \text{Current Rate} \leq \pm 5$ c. $\text{Range Value} \leq \text{Max Range}$ d. $\text{Acceptable Limit} \leq \text{Delta Percent} \leq \text{Service Limit}$ <p>If a parameter meets all the conditions and the Delta Percent is less than the Acceptable Limit, it is excluded from calibration as there is no need for calibration.</p> <p>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.</p> <p>Selecting the check box enables you to manually enter a value in [New Rate (%)]. A range of 80% to 120% may be entered.</p>
14	Select [OK] to update the compensation rates. The calibration process is logged in the calibrator calibration history.

NOTE: If an error occurs during analysis and the analysis can no longer continue, stop precision check. Once the error is cleared, redo the manual analysis.

If calibration fails the first time, notify your supervisor or the Sysmex Field Service Representative. Recalibrate with the same or new lot of calibrators and perform the following:

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1. Select at least 10 different fresh blood samples whose values have been determined by duplicate analysis in another instrument known to be accurately calibrated.
2. If all specimens have less than 15% difference, then the instrument is ready to run.
3. Run the specific level of controls for your shift.
4. If controls are IN, then you can begin processing patient samples.
5. If controls are NOT IN, notify your supervisor, Sysmex Field Service Representative/IR Dept. or call tech support.

Viewing Reports in BCQM

To view a Calibration Verification Certificate:

1	In Calibration History Tab, navigate to the Calibration Verification section of the screen (left side)
2	From the Select A Report drop-down, select CCV Certificate
3	Select analyzer model and serial number.
4	Select the date range, then [Submit]; the report displays.

To view an Evidence Based Calibration Certificate:

1	In Calibration History Tab, navigate to the Calibration section of the screen (right side)
2	Select analyzer model and serial number.
4	Select the date and time, the certificate displays.

Controlled Documents

The following controlled documents support this procedure.

Reference	
1.	Sysmex Product Notification Document Number: 62-1539: XN-L Series™: BeyondCare Quality Monitor and Calibration Verification
2.	Sysmex XN-L Series XN-550/XN-450/XN-350 Basic Operation (North American Edition), Sysmex Corporation, Kobe, Japan.
3.	Sysmex XN-L Series XN-550/XN-450/XN-350 General Information (North American Edition), Sysmex Corporation, Kobe, Japan.
4.	Sysmex XN-L Series XN-550/XN-450/XN-350 Troubleshooting (North American Edition), Sysmex Corporation, Kobe, Japan.
5.	Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).
6.	Sysmex Reagents of America Inc., Mundelein, IL. XN CAL, Hematology Calibrators: Calibrators for Sysmex Hematology XN-L Series Analyzers, package insert.
7.	Sysmex America Inc., Lincolnshire, IL. XN-L CHECK Hematology Control for Sysmex XN-L Series Analyzers package insert.

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8. Sysmex America Inc., Lincolnshire, IL. Sysmex <i>Insight</i> Participant Overview Guide.
9. Sysmex America Inc., Lincolnshire, IL. BeyondCare SM Quality Monitor User Manual
10. Sysmex Reagents of America, Inc. SDS sheets and reagent product inserts.
11. Sysmex America Inc., Lincolnshire, IL. XN-L Applications Manual.
12. CLIA Brochure 3, "Calibration and Calibration Verification" (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6065bk.pdf) Accessed April 10, 2019.
13. US Code of Federal Regulations, Title 42, Chapter IV, Subchapter G, §493.2 (Definitions).
Attachments
A: Sysmex Product Notification Document Number: 62-1539; 7/2019: XN-L Series TM : BeyondCare Quality Monitor and Calibration Verification

