Sysmex XN Calibration & Precision

Policy

Initial calibration is performed during installation by the Sysmex Field Service Representative. Perform calibration as needed, e.g., when QC data is fluctuating. However, if the abnormality in the QC analysis data was caused by an error in the analyzer, degradation of the reagent, or degeneration of the control blood, do not perform calibration. Calibrators traceable to reference methods are used in the calibration of the analyzer.

The laboratory must verify calibration every six months or on an "as-needed" basis to ensure accuracy of system. Calibration verification is also required if one or more of the following occur:

- Critical parts are replaced.
- Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.
- When advised by Sysmex Field Service Representative.

Calibration verification may be performed by review and documentation of commercial control, proficiency testing results and patient control testing results. The operator may calibrate the following parameters using XN CAL and XN CAL PF calibrator: WBC, RBC, HGB, HCT, PLT, PLT-F and RET.

Before calibration, ensure that the XN is both clean <u>and</u> precise.

Safety

All specimens, reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance. Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01.

Reagents

Calibrators

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

2. XN CAL™ PF: for use in calibrating the analyzer for PLT-F (platelet count obtained from the PLT-F channel)

<u>XN CAL/PF Storage</u>: Store the calibrator in a dark refrigerator at 2-8ºC.
<u>XN CAL/PF Stability</u>:

a. Unopened and properly stored, XN CAL is stable until the expiration date printed on the unopened vial.
b. Open vial stability is 4 hours.

Procedure Follow the steps below to do:

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 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: a. Be from a healthy person who is not taking any medication 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	If the tube holder has not ejected out, press the mode switch.
6	Select the **Change Analysis Mode** button on the control menu and select **Whole Blood.**
7	Select **[OK]** to close the dialog box.
8	Select the **Analyzer** menu button on the control menu.
9	Select **[Calibration]** – **[Precision Check]**
10	Mix the vial containing the sample – 10 end-over-end inversions confirming cell button is dispersed.
11	Place the vial in the sample tube holder.
12	Press the **Start** switch on the analyzer a. The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer. b. The tube holder will slide out when analysis is complete.
13	The results are displayed in the **[Precision Check]** analysis dialog box. **NOTE:** 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.
14	When all analysis results satisfy the conditions, select **[OK]** in the dialog box.
15	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.

Procedure, continued

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	If the tube holder has not ejected out, press the mode switch.
3	Select the **Change Analysis Mode** button on the control menu and select **Whole Blood**.
4	Select **[OK]** to close the dialog box.
5	Select the **Analyzer** menu button on the control menu.
6	Select **[Calibration]** – **[Calibrator Calibration]**.
7	Mix the vial containing the calibrator according to package insert.
8	Place the vial in the sample tube holder.
9	Press the **Start** switch on the analyzer a. The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer. b. The tube holder will slide out when analysis is complete.
10	The results are displayed in the **[Calibrator Calibration]** analysis dialog box. **NOTE:** 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	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 of the following criteria, the check box will automatically be selected: a. 80% $\leq$ New Rate $\leq$ 120% b. New Rate – Current Rate $\leq$ $\pm$5 c. Range Value $\leq$ Max Range d. Acceptable Limit $\leq$ Delta Percent $\leq$ Service Limit If a parameter **meets** all of the conditions and the Delta Percent is less than the Acceptable Limit, it is excluded from calibration as there is no need for calibration. If a parameter **does not** meet all of 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.
14	Select [OK] to update the compensation rates. The calibration process is logged in the calibrator calibration history.

Procedure, continued

C. Calibration – XN CAL PF

Step	Action
1	On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is **Ready**.
2	If the tube holder has not ejected out, press the mode switch.
3	Select the **Change Analysis Mode** button on the control menu and select **Whole Blood**.
4	Select **[OK]** to close the dialog box.
5	Select the **Analyzer** menu button on the control menu.
6	Select **[Calibration]** – **[Calibrator Calibration (PLT-F)]**.
7	Mix the vial containing the calibrator according to package insert.
8	Place the vial in the sample tube holder.
9	Press the **Start** switch on the analyzer a. The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer. b. The tube holder will slide out when analysis is complete.
10	The results are displayed in the **[Calibrator Calibration (PLT-F)]** analysis dialog box. **NOTE:** 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 (PLT-F)]** execution dialog box.
13	Select the check box to include the calibration parameter in the calibration (PLT-F) exercise, clear the check box to exclude the parameter in the calibration exercise. If a parameter meets all of the following criteria, the check box will automatically be selected: c. 80% $\leq$ New Rate $\leq$ 120% d. New Rate – Current Rate $\leq \pm 5$ e. Range Value $\leq$ Max Range f. Acceptable Limit $\leq$ Delta Percent $\leq$ Service Limit If a parameter **meets** all of the conditions and the Delta Percent is less than the Acceptable Limit, it is excluded from calibration as there is no need for calibration. If a parameter **does not** meet all of 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.
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:

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.

Reference

1. Sysmex XN-9000 Instructions for Use (North American Edition), Sysmex Corporation, Kobe, Japan.

2. Sysmex XN series Administrator's Guide (North American Edition), Sysmex Corporation, Kobe, Japan

3. Sysmex America Inc., Lincolnshire, IL. XN CAL, XN CAL PF Hematology Calibrators: Calibrators for Sysmex Hematology XN-Series Analyzers, package insert.

4. Sysmex America Inc., Lincolnshire, IL. XN CHECK Hematology Control for Sysmex XN-Series Analyzers package insert.

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Implemented
New	Procedure for new XN instruments.	Julius Salomon, 7/1/17			