



STEM CELL LABORATORY (STCL)



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Sysmex XN-450 Automated Hematology Analyzer Quality Control Management

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SYSMEX XN 450 AUTOMATED HEMATOLOGY ANALYZER

QUALITY CONTROL MANAGEMENT

1 PURPOSE

Quality control is performed in order to monitor an analyzer's performance over time. XN-L CHECK are the materials used to monitor the performance of the XN-450 analyzer. Quality control should be run in accordance with regulatory agency requirements. For the BeyondCare Quality Monitor program, a minimum of 2 levels of controls are needed to be run at least once every 24-hours. It should be noted that for troubleshooting purposes, additional control runs may be necessary. The BeyondCare Quality Monitor program will help determine when troubleshooting is necessary and dynamic screen prompts will guide the end user for the next action. All troubleshooting actions are logged into the Activity Log. *(Refer to the BeyondCare Quality Monitor IFU for full details.)*

BCQM is a web application providing analyzer quality control status and information. This requires an active Sysmex Network Communications System™ (SNCS) connection and automatic transmission of quality control results to the Sysmex *Insight* IQAP program. Comprehensive instructions, details, and graphics can be found in the BeyondCareSM Quality Monitor for Hematology (BCQM) and *Insight*TM User Manual. Access the BCQM program by using the URL: <https://bcqm.sysmex.com>. All laboratory users require an individual log on to review quality control in BCQM. Use of their Sysmex CRC log in credentials should grant them access to BCQM. If a laboratory does not have an SNCS connection or policies do not permit firewall access, they should follow the processes described in Option B below.

Option	Analyzer Model	SNCS	Submission of QC	Review QC in	Use of Lot Calendar Required
A	XN	Required	Automatic as Tested	BCQM > Reports	NA
B	XN	NO SNCS	File Transfer in BCQM>Insight	BCQM > Reports	Yes

2 INTRODUCTION

- 2.1 The Stem Cell Lab runs controls for each shift, approximately every 8 hours. However, QC may not be required/performed on second shift if there are no patient samples that will be run after the initial 8-hour time frame expires. Control runs can also be used for troubleshooting purposes and additional control runs may be completed as necessary.
- 2.2 Sysmex recommends that laboratories establish their own QC Target Values for each new lot number. When the laboratory receives a new control lot, it is analyzed a minimum of 10 times, preferably twice a day for a minimum of 5 days before auto setting target values (setting mean value). Once the auto target values

are set, the user can evaluate the controls by viewing XN-LCHECK Levy-Jennings Charts under the QC Files tab.

3 SCOPE AND RESPONSIBILITIES

- 3.1 This procedure is referenced when entering new control lot data and executing change lot of the Sysmex® XN 450 Automated Hematology Analyzer and when submitting data to BCQM/ *Insight*™. Peer Data
- 3.2 The Medical Directors, Laboratory Manager, Quality Manager, and applicable laboratory staff are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

- 4.1 QC Quality Control
- 4.2 L-J Levy Jennings
- 4.3 GP Graph Printout
- 4.4 LP Ledger Printout
- 4.5 STCL Stem Cell Laboratory
- 4.6 BCQM **BeyondCare Quality Monitor**
- 4.7 *Insight*™ Inter-Laboratory Quality Assessment Program

5 MATERIALS

- 5.1 Supplies
 - 5.1.1 NA
- 5.2 Reagents
 - 5.2.1 Four Sysmex reagents are used on the Sysmex XN 450
 - 5.2.2 All reagents are used at room temperature and are to be used (unopened) within the manufacturer's expiration date on each container.
 - 5.2.3 All reagents are azide free, and they are intended for *in vitro* diagnostic use only. **Do NOT ingest.**

XN-L REAGENTS

CELLPACK DCL
 Lysercell WDF
 Fluorocell WDF
 SULFOLYSER

OPEN EXPIRATION

60 Days
 90 Days
 90 Days
 60 Days

- 5.3 **XN-L CHECK®** (Levels 1-3) manufactured by Sysmex is a whole blood commercial control for use with the Sysmex® XN 450 hematology analyzer.

6 EQUIPMENT

- 6.1 Sysmex® XN 450 Hematology Analyzer (or equivalent)
- 6.2 Graphic Printer

7 SAFETY

- 7.1 Use all appropriate personal protective equipment when handling laboratory controls to include, but not limited to, gloves, lab coats, goggles, etc.

8 PROCEDURE

Registering and modifying a QC file – lot information input

8.1 Method One: Automatic Registering of a QC File – First time analysis of a lot:

8.1.1 Prepare the control material for analysis following the instructions in the package insert.

8.1.2 When the material is ready for analysis, simply run the control using the barcode label on the material vial.

8.1.3 If that lot is not already registered, the XN-L analyzer will setup all lot information without user intervention.

8.2 Method Two: Manual Registration of new lot material

8.2.1 Select [QC File] icon

8.2.2 Select a QC file that does not have a lot registered.

8.2.3 Select [Register]

8.2.4 Select [Read Assay file]

8.2.5 Select the correct QC product, lot number, and level

8.2.6 Select [Ok]

8.2.7 Verify the QC lot number, level and expiration date matches the QC vials received by the lab.

8.2.7 Repeat for each level of XN-L CHECK to be registered.

Automatic BCQM Target/Limit Synchronization

If your analyzer is enrolled in automatic synchronization, your instrument's QC targets and limits will synchronize with BCQM every 24 hours.

- To determine if an analyzer has received a synchronization, compare the MCV target value on the analyzer's L-J chart to the assay target value. If the values are different, the instrument has received at least one automatic sync.
- Note: The MCV value has the most noticeable daily change, which only changes approximately 0.1 fL every 3 days.

New QC lot crossover or parallel studies

As soon as the new QC lot is received, the new lot is analyzed in conjunction with the current QC. The BeyondCare Quality Monitor program establishes the target and limit values for the new QC lot as soon as the first vial of each level gets analyzed.

Reviewing Quality Control Results in BeyondCare Quality Monitor

1. Log into BCQM Application

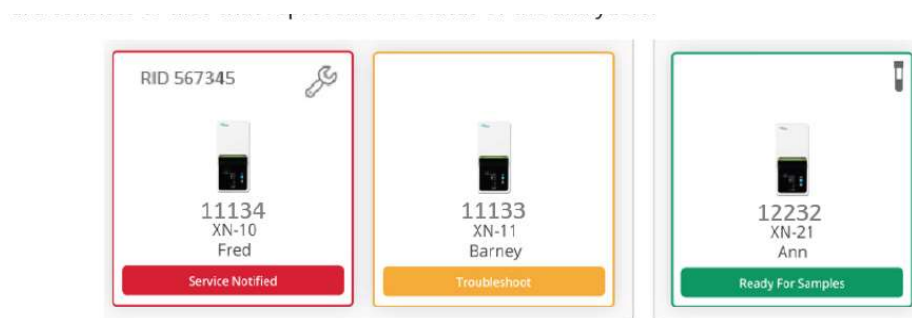
The laboratory user should log into the BCQM software so that the program is visible while running Quality Control samples. The BCQM software application is accessed at: <https://bcqm.sysmex.com>.

Enter your Customer Resource Center (CRC) credentials using your complete email and password. Select LOG IN to continue to the BCQM home screen.

Select the correct laboratory site in the drop-down menu on the left-hand side of the screen.

2. Review of Dashboard Status

The dashboard displayed will contain a list of tiles that represent the status of the analyzers at your laboratory,




The displayed colors indicate the status of each analyzer as follows:

COLOR	STATUS	NOTES
Green	The instrument is ready for samples	
	QC has passed	
	Background has passed	
Yellow	The instrument is not ready for samples	
	QC is overdue	
	QC error is detected	
	Corrective Action Pending	
Red	The instrument is not ready for samples	
	QC error detected and	

	troubleshooting failed.	
	Service is now required due to a detected issue not being resolved by the recommended corrective action.	If the instrument goes to the red status, no further action is required. TAC has been notified and will contact the lab or dispatch a Service Engineer. Hovering over the wrench icon will display the Request ID number.

Troubleshooting Steps Displayed on the Sysmex Dashboard

If QC is unacceptable and the dynamic button displays 'Troubleshooting', click on the message to display details that describe the outlier and status.



11133
XN-11
Barney

Troubleshoot

Resolve QC issue

11003 - XN-10

QC results run within the last hour

Sample Date	Level	Lot	Control Type	Status
01/22/2023 19:01:00	Level 2	2343	XN CHECK	Failed (FCM)

Skip Troubleshooting
Start Troubleshooting

Two buttons will be displayed as:

Skip Troubleshooting

Start Troubleshooting

Resolve QC issue

897886 XN-10

QC results run within the last hour

Sample Date	Level	Lot	Control Type	Status
7/19/2022 10:27 AM	Level 1	0006	XN CHECK	Pass
7/19/2022 10:28 AM	Level 2	0006	XN CHECK	Failed: RBC, FCM, HGB
7/19/2022 10:30 AM	Level 3	0006	XN CHECK	Pass

Skip Troubleshooting
Start Troubleshooting

Once you click on [Start Troubleshooting], another prompt will ask if the QC vial has been open for more than seven days. Select [Yes] or [No].

Resolve QC issue

897886 XN-10

Has the vial been open for more than 7 days?

Yes No

IF the answer is [Yes], a prompt will appear recommending use of a new vial. Click [Next] and follow the recommended instructions.

Resolve QC issue

897886 XN-10

Retrieve and prepare a new vial per proper handling techniques.

Next

A summary of troubleshooting steps performed or skipped will be displayed after following the prompted troubleshooting steps. The QC issue will be identified, and the recommended action will be displayed. This will complete the troubleshooting, and the user will be allowed to add an additional comment.

Comments

897886 XN-10

User:
Jen.User@generalhospital.org

Comments:

1. Complete: Performed Rinse Flowcell
2. Complete: Performed Remove Flowcell air bubbles
3. Complete: Check SLS reagent tubing and replenish reagent
4. Complete: Performed routine cleaning

Additional comments

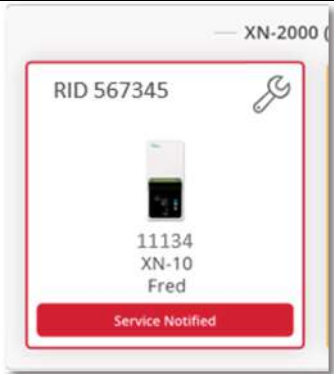

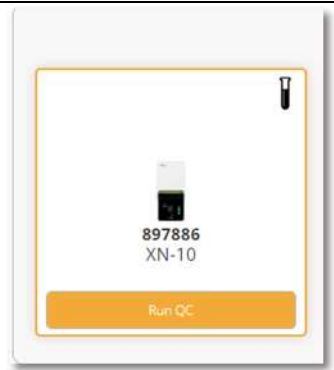

Please add any additional comments then press Complete to return to the Dashboard and run QC.

Complete

Post the completion of troubleshooting steps, select [Complete], return to the Dashboard and analyze Quality Control for review.






Icons that can be displayed in BCQM

Depending on the status of the analyzer, different icons can be displayed as follows:

DISPLAY	IMAGE	NOTES
Red Dashboard		If the instrument displays red status, no further action is required. Sysmex TAC has been notified and will contact the lab or dispatch a Service Engineer. Hovering over the Wrench icon will display the Request ID number.
Vial Icon with Green Dashboard		The [vial icon] is displayed on the green tile when the instrument is ready for samples. Hovering over the icon displays the date and time QC is due.
Vial Icon with Yellow Dashboard		The [Vial Icon] with Yellow Dashboard is displayed when QC is overdue. The dynamic action button will display <i>Run QC</i> .
Wrench Icon with Red Dashboard/ Under Service		The [Wrench icon] is displayed if the instrument is being serviced. The service request ID number will be displayed next to the Wrench icon.

Display of Quality Control Data, Charts, and Options in BCQM

Several options exist for the display and review of Quality Control data in BCQM. All formats and options are extensively described in the BeyondCareSM Quality Monitor for Hematology (BCQM) and *Insight*TM User Manual (CF-07495)

DATA REVIEW OPTION	IMAGE	NOTES
Plot View		Each plot represents the QC data run at the specific time and date. The column on the left represents the BCQM ranges and limits percentage. A separate graphic is used per level of QC material.
L-J Plot View with instrument comparison		This option allows the review of Quality control data in L-J format along with comparison to an alternate analyzer.
Data View		The data view allows the user to view each QC with the numeric value. Filtering, addition of comments, and the use of 'managed' and 'unmanage' data options are present.
Shift Activity		The Shift Activity option provides detailed information for each shift. The list of information can be obtained from this report. Each activity would indicate the date, time and user ID. The user can add a comment on each activity if needed.
QC Task Filter		The QC Task filter will allow review of all of the QC plots that are out of range, add comments, and unmanage the data run. Any QC runs left ignored in the QC Task filter view will stop BCQM from monitoring QC. BCQM will also stop sending alerts to Sysmex TAC. To re-enable BCQM's monitoring and alerts to TAC, remove the QC runs from the QC Task Filter by either adding comments or marking the QC run as unmanaged and adding comments.

Recording and Storage of Quality Control data

The BeyondCare Quality Monitor application stores the last 2.5 years of QC data on demand. All QC data older than 2.5 years is archived.

Printing and saving QC Data

- Select [QC Files] icon and highlight file to output.
- Select [QC Chart] icon.
- Set the Range of points to output by clicking [Range] and capturing the points with the cursors.
- Select [Output] to print the selected chart to either GP or LP.
- Select [File] to save the data to removable media.
- **NOTE:** Comments that were added to the data do not print on the GP and LP report.

In the event SNCS (Sysmex network communication system) loses connection:

- a. BeyondCare Quality Monitor becomes unavailable until SNCS connection is restored.
- b. Review the QC files on the analyzer IPU.

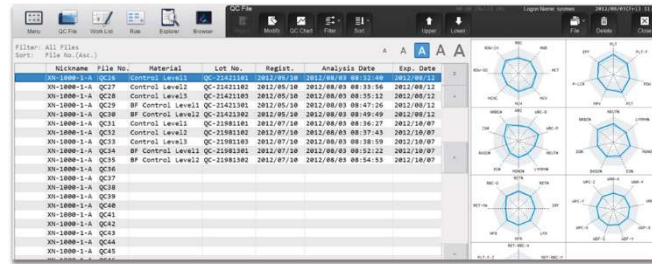
Manual Upload of QC file data to BCQM / *Insight Peer Data*

The QC upload function allows the users to upload QC manually if the selected analyzer does not support real-time QC or if your analyzer is not connected to the Internet. Quality Control data submitted into the peer group program can be reviewed in a comprehensive report format with statistical and graphical presentation of analyzer performance. Review codes are shown for bias, SD, and CV warnings. Historic trending of the analyzer to group for CV and SDI can be found in the History section of the report. For more details, please refer to Appendix 3 of the BeyondCare Quality Monitor for Hematology.

1. Click on the QC File on the Main Menu of the analyzer.



- Highlight the QC file to be saved, click on the File icon.

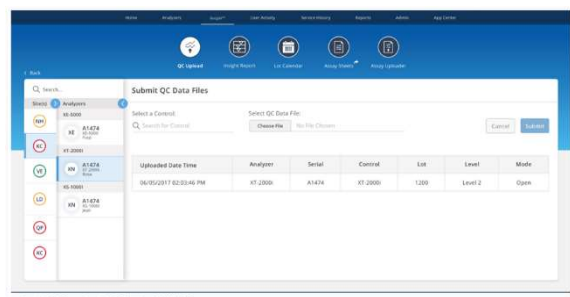


- Select Output in Sysmex *Insight*.



You will see a pop-up message that the file is being saved.

- Repeat the steps above to save QC file data for all levels and/or lot numbers needed.
- Safely remove the USB drive from the XNL computer and take it to a computer with internet access to upload the data for peer group submission using the BCQM > *Insight* icon.
- To upload a saved QC file:
 - Using a computer with internet access, log into the BCQM application using: <https://bcqm.sysmex.com> and your CRC log in credentials. Connect the USB drive to the workstation.
 - Select the desired analyzer from the list on the left-hand side.
 - Click *Search for Control* and select the correct control material. (Only applicable QC material types will be shown.)
 - Click [*Chose File*] to browse your QC file.
 - After selecting the QC file on the USB, click [*Submit*] to upload that QC file.



- When QC is successfully uploaded, a message box is displayed stating 'Uploaded Successfully'.
- Review the Lot Calendar due dates for QC submission guidelines. Each lot has two data submission dates, approximately every 30 days for the 84-day dated product.
- Data may be managed in the XNL-IPU and/or in *Insight*. See *Insight* documentation for guidance on *Insight* processes and report interpretation guides.
- Review *Insight* generated reports, sign & date per your laboratory requirements.
- If assistance is needed with reports or quality control recovery, consult Sysmex Technical Assistance Center at 1-888-879-7639.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-EQUIP-023 Sysmex XN-450 Hematology Analyzer Automated Blood Count Procedure for the STCL
- 9.2 STCL-EQUIP-023 FRM 1 Sysmex XN-450 QC Review Log – DAILY
- 9.3 STCL-EQUIP-023 FRM 3 Sysmex XN-450 QC Review Log – Weekly/Monthly

10 REFERENCES

- 10.1 Sysmex XN-450 Instructions for Use
- 10.2 XN-L CHECK Hematology Control for Sysmex® XN-LSeries Analyzers
- 10.3 *Insight*™ Website Upload and Data Entry Instructions
- 10.4 *Insight*™ Managing Your QC Data Instructions

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	B Waters-Pick	New Document

Signature Manifest**Document Number:** STCL-EQUIP-023 JA1**Revision:** 01**Title:** Sysmex XN-450 Automated Hematology Analyzer Quality Control Management**Effective Date:** 20 Mar 2025

All dates and times are in Eastern Time.

STCL-EQUIP-023 JA1 Sysmex XN-450 Automated Hematology Analyzer Quality Control Management**Author**

Name/Signature	Title	Date	Meaning/Reason
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Management

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		19 Mar 2025, 11:21:23 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
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Quality

Name/Signature	Title	Date	Meaning/Reason
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Document Release

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Amy McKoy (ACM93)	Document Control Specialist	20 Mar 2025, 01:40:02 PM	Approved