SYSMEX XN 530 & CBC SAMPLE PROCESSIN

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SUPERSEDES: Procedure titled _____

I. PRINCIPLE

The Sysmex XN-550/XN-530 is a multi-parameter quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 27* whole blood diagnostic parameters and 7* body fluid diagnostic parameters. This instrument is used in screening patient populations found in clinical laboratories. This instrument enables quantitative, identification, and existence ratio analysis of tangible components of blood, (red blood cells, white blood cells, platelets, and other cells).

The XN-550/XN-530 performs hematology analyses based on the hydrodynamically focused impedance measurement, the flow cytometry method (using a semiconductor laser) and the SLS-hemoglobin method.

The analyzer counts and sizes red blood cells (RBC) and platelets (PLT) using hydrodynamic impedance counting (sheath flow DC method). At the same time the hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood via the RBC pulse height detection method.

Flow Cytometry is used to analyze physiological and chemical characteristics of cells and other biological particles. Flow cytometry is a method used to analyze those cells and particles as they pass through extremely small flow cells.

Directly Measured Parameters: WBC, RBC, HGB, HCT, RDW-SD, PLT-I, NEUT%, LYMPH%, MONO%, EOS%, BASO%, IG%, WBC-BF*, RBC-BF*, TC-BF*, BF-PMN%*, BF-MN%*, RETIC%*, RET-HE*, IRF%*.

Calculated Parameters: MCV, MCH, MCHC, RDW-CV, MPV, NEUT#, LYMPH#, MONO#, EOS#, BASO#, IG#, RETIC#*, BF-PMN#*, BF-MN#*.

II. SPECIMEN REQUIRMENTS

A. Required specimen

1. Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.

B. Specimen volumes required

1. Optimal draw is a 12 x 75 tube filled to capacity. Follow the instruction collection tube manufacturer's data for specific information on tube minimum and maximum fill volumes.
   NOTE: The minimum volumes stated below are those required for appropriate sampling by the analyzer.
2. A minimum of 1 mL of whole blood is required for sampler analysis.
3. Manual analysis whole blood mode
   a. Closed tube – 1 mL minimum sample volume, 25 µL is aspirated.
   b. Open tube – 300 µL minimum sample volume, 25 µL is aspirated.
   c. Raised Bottom Tube – RBT micro collection tube – 250 µL minimum sample volume, 25 µL is aspirated.
   d. Open microtube – 100 µL minimum sample volume, 25 µL is aspirated.

C. Unacceptable specimens

- Those containing fibrin or clots
- Excessive platelet clumping
- Substandard mixing or collection
- Expired or improperly stored collection tubes
- Improperly filled tubes based on collection tube manufacturer's guidelines
- Specimens contaminated with IV fluid
- Quantity not sufficient sample (QNS)

In addition, XN-L series systems provide options to customize flagging and rules to identify samples with **platelet clusters or fibrin**.

***Note**: Clotted or QNS samples should be phoned immediately to the ward/ clinic and fresh repeat specimen requested.*

D. Characteristics that may affect test results:

- Lipemia,
- Icterus
- Hemolysis
- Cold agglutinins.

E. Stored Specimen Stability

1. EDTA blood samples should be analyzed within **4 hours** whenever possible.
2. If samples cannot be analyzed within 4 hours, store in a refrigerator at 2-8°C.
3. Sample **stable for 24 ours at room** temperature and **72 hours/3 days** refrigerator at 2-8°C.
4. Allow refrigerated samples to come to room temperature and mix well before analysis.

4. Do not place CBC and Diff samples on a mechanical rocker. Constant rocking may alter white cell membranes, resulting in false interpretive messages.

Sample received from outpatient clinic must kept at refrigerator at 2-8°C during transportation

WARNING:	All patient specimens should be considered potentially infectious and must be handled with precautions used for human blood, as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR part 1910.1030. Follow specimen handling as outlined by laboratory safety policy.
Recommended:	Wear gloves and a lab coat. Wear safety glasses if there is a risk of splashing.

III. SUPPLIES & REAGENTS

A. Supplies

1. Test tubes
2. CELLCLEAN® AUTO
3. Sysmex reagents
4. Commercial Quality Controls; XN-L CHECK™ or XN CHECK™

B. Sysmex Reagents

1. Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-550/XN-530 Series modules.
2. All reagents are used at room temperature and are to be used within the manufacturer's expiration date on each container.
3. Record date received and date opened on container.
4. All reagents are azide free and are intended for *in vitro* diagnostic use only. **Do not ingest.**

XN-L REAGENTS	OPEN EXPIRATION
CELLPACK™ DCL	60 Days (20L/10L)
CELLPACK DST*	60 Days (20L / 2 x 4L)
CELLPACK DFL*	60 Days

SULFOLYSER™	60 Days (3 x 500mL) *XN-530 only*
	60 Days (2 x 1.5L)
Lysercell™ WDF	90 Days (2 x 4L)
Lysercell WDF	90 Days (2L) *XN-530 only*
Fluorocell™ WDF	90 Days (2 x 42mL)
Fluorocell WDF	90 Days (2 x 22 mL) *XN-530 only*
Fluorocell RET*	90 Days
CELLCLEAN AUTO	Single Use Vial

**Dependent upon activated license, this lab is not reporting RET*

C. Diluents

1. CELLPACK DCL: Whole blood diluent for use in hematology analyzers.

CELLPACK DCL Storage

a. Store at 2°-35°C away from direct sunlight.
b. If frozen, thaw and mix thoroughly before using. Allow bubbles to dissipate before use.
c. CELLPACK DCL is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace container.

CELLPACK DCL Stability

a. Unopened, stable until expiration date printed on the container.
b. Opened, stable for 60 Days.

CELLPACK DFL Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. ***CELLPACK DFL does not have ingredients with those characteristics.***

D. Lysing Reagents

1. SULFOLYSER (SLS): Reagent for the automated determination of hemoglobin concentration of blood. Sulfolyser is lysing reagent that releases the hemoglobin to be measured by the SLS hemoglobin method.

SULFOLYSER Storage

a. Store at 1°-30°C away from direct sunlight.
b. If frozen, thaw and mix thoroughly before using.
c. Allow the container to equilibrate to environmental temperature (15-35°) prior to use.
d. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

SULFOLYSER Stability

a. Unopened, stable until expiration date printed on the container.
b. Opened, stable for 60 Days (1.5L) or 90 Days (5L).

SULFOLYSER Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS documentation of ingredients which have been determined to

be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. ***SULFOLYSER does not have ingredients with those characteristics***.

2. Lysercell WDF: Reagent product to be combined and used with Fluorocell WDF. By hemolyzing red blood cells with Lysercell WDF and dying the white blood cell component with Fluorocell WDF, the counts and percentages of neutrophils, lymphocytes, monocytes, eosinophils and basophils are analyzed.

Lysercell WDF Storage

a. Store at 2°-35°C away from direct sunlight.
b. Use at an environmental temperature (15-35°)
c. Do not use the reagent if it is suspected to have frozen.
d. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

Lysercell WDF Stability

a. Unopened, stable until expiration date printed on the container.
b. Opened, 1L stable for 60 days, 2 x 4L stable for 90 days.

Lysercell WDF Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. ***Lysercell WDF does not have ingredients with those characteristics***.

E. Staining Reagents

1. Fluorocell WDF: Used to stain the leukocytes in diluted and lysed blood samples for determination of differential count in blood.

Fluorocell WDF Storage

a. Store at 2°-35°C in a dark place.
b. Do not use the reagent if it is suspected to have frozen.

Fluorocell WDF Stability

a. Unopened, stable until expiration date printed on the container.
b. Opened, stable for 90 Days.

Fluorocell WDF Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Refer to the SDS.

2. Fluorocell RET*: Used to stain the reticulocytes in diluted blood samples for the assay of reticulocyte count, reticulocyte percent in blood.

Fluorocell RET Storage

a. Store at 2°-35°C in a dark place.
b. Do not use the reagent if it is suspected to have frozen.

Fluorocell RET Stability

a. Unopened, stable until expiration date printed on the container.

b. Opened, stable for 90 Days.

Fluorocell RET Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Refer to the SDS.

F. Cleaning Agent

1. CELLCLEAN AUTO: Detergent for fully automated hematology analyzer. This is used as a strong alkaline detergent to remove lysing reagents, cellular residuals, and blood proteins remaining in the hydraulics of the analyzer on XN-L Series automated hematology analyzers.

CELLCLEAN AUTO Storage

a. Store at 1-30° C, away from direct sunlight.
b. Do not use the reagent if it is suspected to have frozen.

CELLCLEAN AUTO Stability

a. Unopened, stable until expiration date printed on the container.

CELLCLEAN AUTO Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. ***Refer to the SDS, CELLCLEAN AUTO is corrosive and may cause burns to skin.***

G. Commercial Quality Control Material for XN-550/XN-530 analyzers

1. **XN- L CHECK or XN CHECK**
   a. Manufactured by Streck, available as a tri-level package.
   b. Whole blood commercial control used to monitor performance of all XN-550/XN-530 analyzers.
   c. Formulation
      1. XN CHECK Consists of human red and white blood cells with a platelet component suspended in fluid medium. XN-L CHECK consists of human and/or animal red and white blood cells with a platelet component suspended in fluid medium.
      2. Each vial contains 3 mL of control material.
   d. Storage
      1. Store vials at 2-8°C
      2. Do not freeze or expose to excessive heat.
   e. Stability
      1. Unopened and properly stored, XN-L CHECK and XN CHECK is stable until the expiration date printed on the unopened vial.
      2. Open vial stability is **15 days for XN-L CHECK** and **7 days for XN CHECK** when promptly refrigerated after each use.
      3. Record the date on each vial upon opening or cap piercing.
      4. Heat or freezing can damage XN-L CHECK/XN CHECK without gross visible changes. Moderate hemolysis can be normal. ***Deterioration is suspected when the mean of the control results is not within the assay expected ranges after appropriate troubleshooting.***

5. If deterioration is suspected, call the Sysmex Technical Assistance Center. 1-888-879-7639 (1-888-8SYSMEX)

WARNING: POTENTIALLY INFECTIOUS MATERIAL. The human blood used in XN-L CHECK, XN-CHECK, XN-CHECK BF is non-reactive for Hepatitis B Surface Antigen and negative for antibodies to HIV-1, HIV-2, and Hepatitis C Virus using FDA specified techniques. However, no current tests can assure the absence of these pathogens. XN-CHECK, XN-L CHECK, XN-CHECK BF should be considered potentially infectious and must be handled with precautions used for human blood as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR, 1910.1030.

H. Calibrators

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

XN CAL Storage

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

XN CAL Stability

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.**

WARNING: Risk of Infection Always wear PPE when using control blood products. Also, wash your hands after completing the process. The basic blood used in the control blood has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle it with the same level of care used when handling other blood samples that may be infectious.

I. XN-550/XN-530 Reagent Replacement

1. When the replacement of reagent is required, an error message appears. Promptly acknowledge the error message by clicking execute to enter the reagent replace dialog box and proceed to replace the indicated reagent. **Verify that "CAPS LOCK is off**.
2. Replacing a new diluent / hemolytic agent
   a. Touch the name of the reagent to be replaced.
   b. Place a check-mark next to 'Replace the reagent,' then place the cursor in the reagent code text box.
   c. Using the hand-held reader, scan the reagent code on the new reagent container. **NOTE:** Scan Reagent Code 2 when available on the reagent container.
   d. Remove the cap from the expired/empty container and carefully remove the spout.
   e. Pull out the dispensing, set straight up.
   f. Insert the dispensing set straight into the new reagent container and close the cap.
   g. Select [Execute]
      a. Reagent replacement starts. When complete, the dialog box closes automatically.
3. Replacing CELLPACK DST with a RU-20* *(if applicable)*

   Instructions for replacing CELLPACK DST are located in the RU-20 CLSI guideline and RU-20 Quick Guide.
4. Replacing Dye

a. Display the [Reagent Replacement] dialog box.
b. Prepare the new reagent cartridge.
    1. Confirm the reagent has not expired.
c. Pull out the dye holder.
d. Slowly remove the dye cover, taking care that dye does not drip.
e. Remove the entire dye holder.
    1. When the dye holder is removed, a Help dialog box appears in the IPU screen.
f. Remove the old reagent cartridge from its holder.
g. Install the new reagent cartridge into the holder
    1. Make sure the color of the label on the new reagent cartridge matches the color of the dye cover and install. Analyzer will beep as confirmation of new reagent installation.
    2. If the wrong reagent is installed, the analyzer beeps repeatedly and the Help dialog box appears in the IPU screen.
h. Place the dye cover.
    1. Place into dye holder.
    2. The ID of the new reagent is read automatically and the information is registered.
i. Close the dye holder.
    1. Reagent replacement starts.
    2. When complete, the reagent replacement window closes automatically.

- ***CAUTION:***
- Do not use the reagent outside of the written intended use, or not according to the written directions for use.
- When replacing this reagent, do not refill and use the same container.
- Handle the reagent with care to prevent air bubbles from foaming.
- Do not use expired reagents.
- If the reagent is removed after it has been connected, (i.e. opened), it may become contaminated with bacteria causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
- NEVER allow contact of the reagent with the human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water and seed immediate medical attention. If swallowed, seek medical advice immediately.
- Before use, please read the safety data sheet carefully.

Upon successful completion of a reagent replacement, reagent information is automatically stored in the **Reagent Replacement Log** located in the **History icon** on the Main Menu.

IV. PRECISION and CALIBRATION

Reference documents located on the CRC for additional guidance:

- *"BeyondCare℠ Quality Monitor for Hematology IFU"*
- *"BeyondCare Quality Monitor for Hematology Inspection Guide"*
- *"Managed Calibration Addendum CLSI"*

Initial analyzer precision and calibration is performed during installation by the Sysmex Service Engineer (SE). ***Calibrators traceable to reference methods are used in the***

calibration of the analyzer. Documentation of parameters that can be calibrated and reference methods for calibrator assay value assignments are contained in the calibrator package inserts.

The calibration of Sysmex hematology analyzers does not expire and is not reagent lot dependent. Per the XN-L-Series IFU, calibration should be performed ***only when indicated***.

Calibration verification, generally required at least every 6 months by regulatory agencies, may be performed by:

- Following manufacturer's instruction for instrument operation
- Testing at least two levels of control materials each day, whereby the controls meet the laboratory's criteria of acceptability.
- Review and documentation of commercial QC and X-BarM QC data
- Proficiency testing results
- Patient control testing results.

Calibration verification may also be accomplished by processing a commercial calibrator and comparing results to those published on the calibrator assay sheet.

Calibration of an analyzer should only be completed when:

- Installation activity occurs
- Critical parts or assemblies are replaced. ***(See "Managed Calibration Addendum" for a reference of critical parts for your analyzer.)***
- Calibration Verification fails (QC values are outside of acceptable limits) and troubleshooting indicates that there is no major underlying problem with the analyzer, reagents or quality control materials.
- When advised by a Sysmex Representative.

The lab will follow the manufacturer recommendation for calibration, however calibration verification will be printed monthly comparing laboratory performance with group mean using minimum of 2 commercial quality controls as per **BeyondCare Quality Monitor for Hematology (BCQM^h)** ***and as followes:***

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. The 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 controls 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 the 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. CCV report will be print/reviewed and approved monthly

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 the precision and calibration (accuracy) of the analyzer.
- Documentation of calibration verification results and generation of a calibration verification certificate for laboratory records.

MMCCL utilizing the BeyondCare Quality Monitor (BCQM^h) Option A

V. QUALITY CONTROL

Quality control is performed in order to monitor an analyzer's performance over time. XN CHECK or XN-L CHECK, are the materials used to monitor the performance of the XN-550/XN-530 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 day test performed. 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 in 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 BeyondCare℠ Quality Monitor for Hematology (BCQM) and *Insight*™ 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.

Option	Analyzer Model	SNCS	Submission of QC	Review QC in	Use of Lot Calendar Required
*A	XN	Required	Automatic as Tested	BCQM > Reports	NA

A. XN-L CHECK Commercial Controls Instructions for Use

1. Remove vials from the refrigerator and allow them to come to room temperature (18-25°C), for approximately 15-30 minutes.
2. Mix vials according to the package insert accompanying the product until the cell button in the bottom of the vial is completely suspended.
3. Perform a close visual inspection of each vial confirming the cell button is completely removed from the bottom of the vial and cellular elements are uniformly suspended with no aggregates.

WARNING: POTENTIALLY INFECTIOUS MATERIAL. The human blood used in XN CHECK, XN-L CHECK, XN CHECK BF is non-reactive for Hepatitis B Surface Antigen and negative for antibodies to HIV-1, HIV-2, and Hepatitis C Virus using FDA specified techniques. However, no current tests can assure the absence of these pathogens. XN-L CHECK should be considered potentially infectious and must be handled with precautions used for human blood as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29CFR, 1910.1030.

C. Frequency of Control use and review

XN CHECK/XN-L CHECK control levels: _Every day patient testing performed

The supervisor reviews the following QC reports at the following intervals:

*If utilizing the **BCQM^h program, the supervisor reviews the BCQM^h reports at the following intervals:***

- Group Comparison Report **every month**
- Continuous Calibration Verification Certificate (CCV) **every month**
- Calibration Certificates (EBC) every calibration.
- Parameter Report **every month**
- Traceability Report **every month**
- ***Insight*** Peer Group Report

D. Registering and modifying a QC file – lot information input

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

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

- When the material is ready for analysis, simply run the control using the barcode label on the material vial.
- If that lot is not already registered, the XN-L analyzer will setup all lot information without user intervention.

E. XN-L CHECK QC Analysis

1. Confirm the analyzer is in a Ready state.
2. Touch [Mode] on the control Menu.
3. Touch the Analysis Mode. Select Whole Blood.
4. Touch OK.
5. Open sampler adaptor and place tubes in sample adapter.
6. Touch Sampler, then touch screen to indicate Starting Tube Position.
7. Touch OK.
8. Close Sampler adapter holder.
9. Press the start switch.
10. Check the analysis results.

G. Automatic BCQM Target/Limit Synchronization

MMCCCL analyzer is enrolled in automatic synchronization, 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.

H. 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.

I. Reviewing Quality Control Results in BeyondCare Quality Monitor

1. Log into BCQM Application

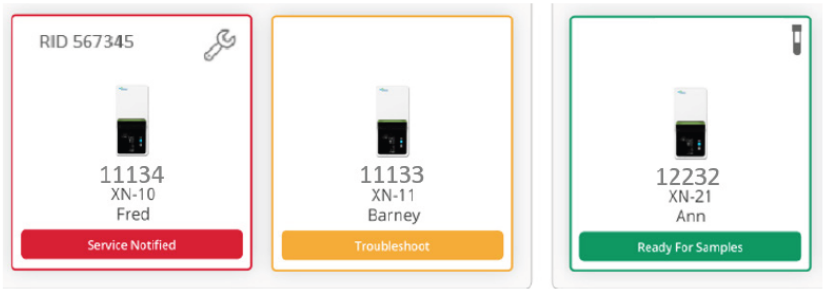
   The laboratory user should log into the BCQM software so that the program is visible while running Quality Control samples. The BCQM software application is accessed at: https://bcqm.sysmex.com.

   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.

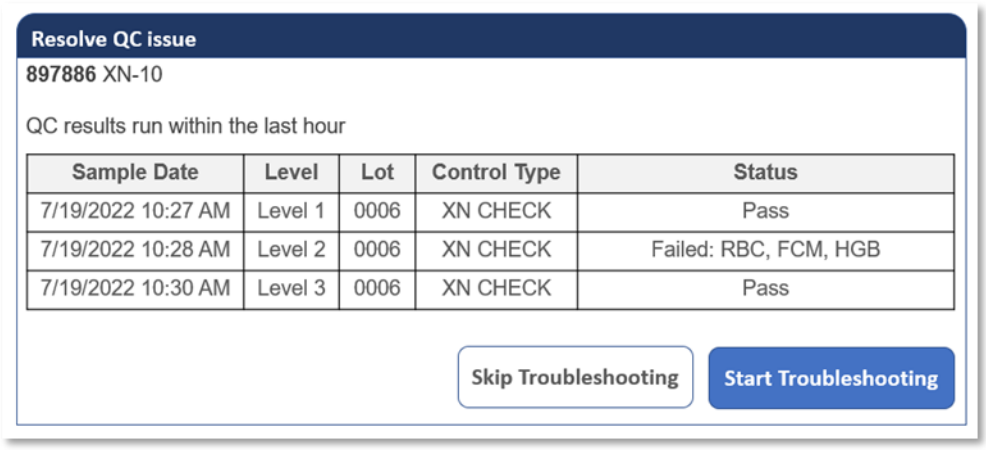
Troubleshooting Steps Displayed on the Sysmex Dashboard

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

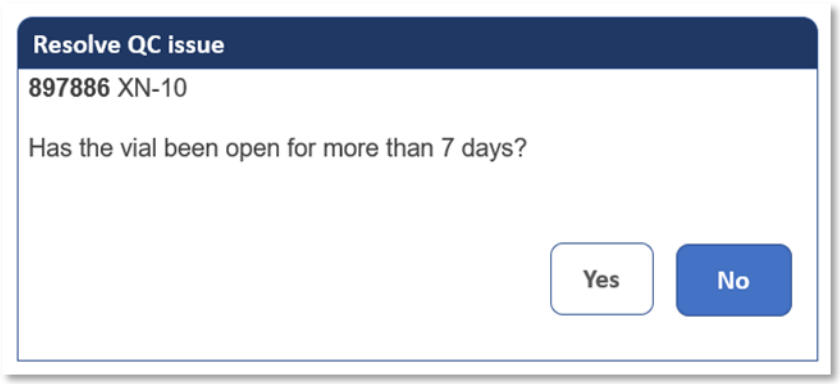
Two buttons will be displayed as:

Skip Troubleshooting

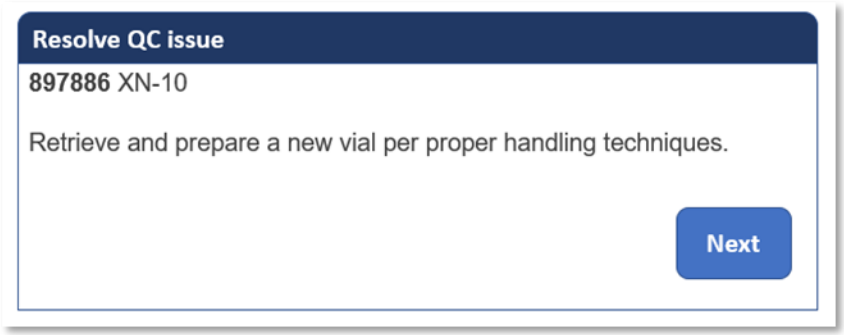
Start Troubleshooting



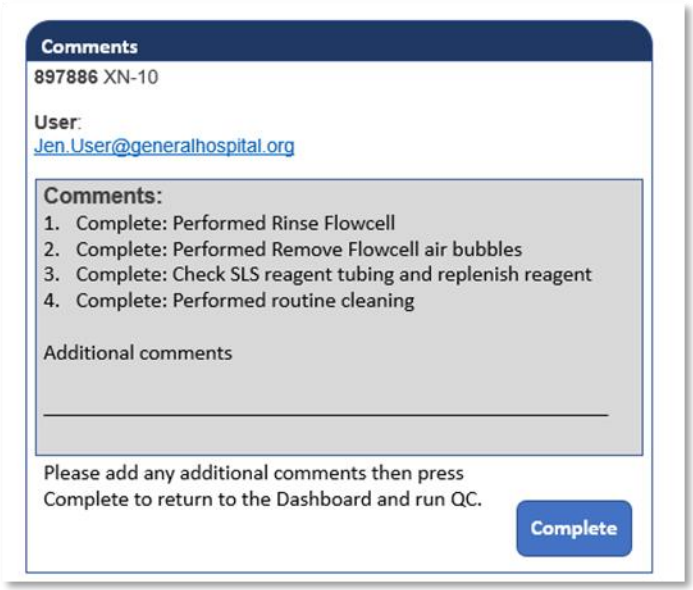
Once you click on [Start Troubleshooting], another prompt will ask if the QC vial has been open for more than seven days. Select [Yes] or [No].



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



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.

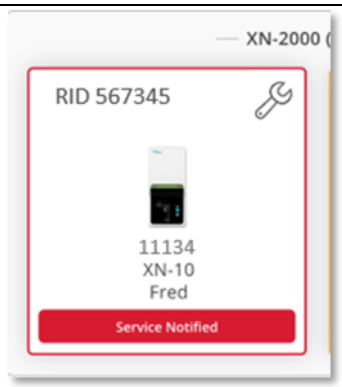
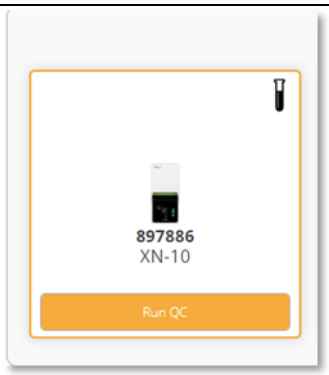


Post the completion of troubleshooting steps, select [Complete], return to the Dashboard and analyze Quality Control for review.

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 *Run QC.*
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 BeyondCare^{SM} 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.
Pattern View		The Pattern view allows review of trending of QC data points, normalization of quality control data per parameter, and a status flag indicating pass or fail per day for calibration verification.
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 runes from the QC Task Filter by either adding comments or marking the QC run as unmanaged and adding comments.

J. Laboratory Specific Troubleshooting Information

MMCCCL will follow BCQM guidelines for troublshooting.

K. 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 of archived.

L. Printing and saving QC Data

- Select [QC Files] icon and highlight file to output.
- Select [QC Chart] icon.
- Set 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.

N. X-barM Moving Patient Averages

1. Establishing X-barM Limit%.
   State how your lab established targets and limits for X-barM. The Sysmex data center suggests using 200 data points representing 4000 samples in 20 patient size batches. Data will be collected over multiple reagent lots and over at least one month including all types of patient samples normally encountered.
2. Batch size and review frequency
   Complete this section with your lab's batch size and chart review frequency. X-barM can be monitored in lieu of a retained patient sample for a longitudinal control if 100 or more patients are run each day. Common batch size is 20; however, the Sysmex data center suggests using a larger batch size to allow about six points to be plotted per 24-hour period. Include when and whether X-barM will be turned off for specific groups of patient specimens to avoid QC error messages related to population shifts.

Our batch size for X-barM is **20** patient samples per batch. Each point on the X-barM graph represents one batch.

Supervisor will review X-barM charts every **28-31** days.

Note: Even if you decide not to use X-barM as part of your quality control program, it is still highly recommended that you leave it on to collect data for troubleshooting purposes. X-barM provides valuable information that assists Sysmex Field Service and Applications associates when troubleshooting analyzer performance issues. The X-barM limits may be widened to avoid X-barM control errors. If you decide to not use X-barM as a quality control tool and leave it on for troubleshooting, it is recommended that you describe this in your local operating procedures.

- Touch the [QC] icon in the [Menu] screen.
- Select X-barM Setting.
- Click [Execute] to perform X-barM Control, Click [Cancel] to deactivate.
- Click [OK].

X-barM control Error Review

Laboratory staff will review X bar M, whenever face [rpblem with QC to help in troubleshooting.

Activating / deactivating X-barM Control

- Touch the [QC] icon in the [Menu] screen.
- Select X-barM Setting.
- Click [Execute] to perform X-barM Control, Click [Cancel] to deactivate.
- Click [OK].

XN-L CHECK control levels: Run every day perform testing and before reporting patients results.

The supervisor reviews commercial and X-barM charts every Week.

NOTE: Periodic display of a message to prompt the user to perform quality control tasks is available through the QC Settings Menu.

A. Registering and modifying a QC file – lot information input

1. Select [QC File] icon.
2. Select a QC file that does not have a lot registered.
3. Insert USB memory stick containing assay file obtained from *Insight.*
4. Select [QC File] button on toolbar.
5. Select a QC file that does not have a lot registered.
6. Select [Regist] button on toolbar and [Input Lot Information] dialog box appears.
7. Touch [Read Assay File]. The [Read Assay File] dialog box appears.
8. Choose appropriate QC file to be registered and press [OK]. The contents of the selected assay file are read and set in the items. Repeat for all three levels taking care to select the appropriate QC file.
9. Remove the USB memory stick if applicable.
10. Confirm that all values are set for each level.
11. Proceed to step 15 if limits have been entered.
12. If manually entering QC limits, Select [Target/Limit Settings]
    a. Select parameter and enter Limit Range %.
    b. Enter for all parameters then select [OK]
    c. Select [OK].
13. Repeat for each level of XN-L CHECK, XN CHECK BF to be registered.
14. To modify an existing QC File, select the QC File and [Modify] from the toolbar. Update the Lot No, Exp. Date as appropriate.
15. Perform parallel studies between production lot and new lot prior to production lot expiration.

B. XN-L CHECK QC Analysis

1. Place the vial containing control blood in the sampler adaptor.
2. Place sampler adaptor in the sampler adaptor holder.
3. Touch the Sampler Start Switch.
4. Results will be plotted on the L-J Chart as well as the Radar Chart for review.

C. Auto-set Targets

1. Parallel test new controls by analyzing the chosen levels of control, selected per lab policy QC protocol, a minimum of twice a day for 5 days or once a day for 10 days prior to expiration of previous lot. After a minimum of 10 data points are accumulated, auto-set the targets.
2. Select QC Chart
3. Select [Range] and set cursors so that every data point is included.
4. Select [Modify].
5. Select Target/Limit.
6. Check Select All and select [Auto Setting]
7. Confirm that the check box for TARGET ONLY is set. Do not select the check box for LIMIT.
8. Select [OK]; the target for each parameter will be calculated and set for the duration of the QC lot.
9. Repeat steps for each new lot of QC being moved into production.

10. Confirm the targets set fall within the range of means provided on the XN-L CHECK assay sheet provided.

D. Reviewing Quality Control Results

1. QC File screen
   - Allows for review of the latest QC results in Radar Chart format for the QC file that is selected in the list.
   - Any point exceeding the upper or lower limit is marked with a red "X".
2. QC Chart screen
   - Allows for review of detailed graph data of all QC runs for selected file.
   - Analysis data is plotted cumulatively and displayed in the chart area as a line graph.
   - Any point exceeding the upper or lower limit is marked with a red "X".
   - User must scroll up and down through the chart to view all parameters for each run.
   - Select [Range] to set a main cursor and a sub-cursor so that data between the two cursors can be manipulated.
   - Statistics may be analyzed over any selected range.
   - Targets may be auto-set for the selected range.
   - To cancel range mode, select [Range] on the toolbar again or exit QC Chart mode.
3. ***Follow laboratory protocol for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability. Complete this section with your laboratory's QC action plan for out of range commercial control products and X-barM.***

E. Quality Control Management

1. From the QC Chart view, select the [**Manage**] button on the toolbar.
2. Select Cursor Data Management.
3. Specify whether a QC run should be excluded from quality control
4. Select [**Not Manage**] to **exclude data from the following**:
   - Statistical computations (SD, Mean, CV)
   - Variable target computation
   - Number of data points = n
5. An open circle will be displayed on the L-J Chart when the QC run is not managed or excluded and is not connected by a line to the adjacent QC runs.

NOTE: XN-L Managed and Not Managed comments and results **"Do Not"** upload to ***Insight.*** To keep ***Insight*** consistent with the QC file on the XN-L analyzer, log into ***Insight*** and manage the same data point.

6. A comment may be added to the QC data selected by the cursor.
   - Select [Any Comment] to input a free text comment.
   - Select [Comments Settings] to use a comment from a list of preset comments in the QC settings menu.
   - Select [OK]
   - A comment bubble will be displayed when a comment exists for a QC run.

- The comment will be visible in the comment display area when the cursor is placed on the QC run.

F. Recording and Storage of QC Data

1. Printing and saving QC Data

   - Select [QC Files] icon and highlight file to output.
   - Select [QC Chart] icon.
   - Set 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.

L. X-barM Moving Patient Averages

1. Establishing X-barM Limit%

   MMCCL will be using 200 data points representing 4000 samples in 20 patient size batches. Data will be collected over multiple reagent lots and over at least one month including all types of patient samples normally encountered.

2. Batch size and review frequency

   MMCCL will use X-barM can be monitored in lieu of a retained patient sample for a longitudinal control if 100 or more patients are run each day. Common batch size is 20; however, the Sysmex data center suggests using a larger batch size to allow about six points to be plotted per 24-hour period. Include when and whether X-barM will be turned off for specific groups of patient specimens to avoid QC error messages related to population shifts.

   Our batch size for X-barM is 20 patient samples per batch. Each point on the X-barM graph represents one batch.

   Supervisor will review X-barM charts every month.

   Note: Even if you decide not to use X-barM as part of your quality control program, it is still highly recommended that you leave it on to collect data for troubleshooting purposes. X-barM provides valuable information that assists Sysmex Field Service and Applications associates when troubleshooting analyzer performance issues. The X-barM limits may be widened to avoid X-barM control errors. If you decide to not use X-barM as a quality control tool and leave it on for troubleshooting, it is recommended that you describe this in your local operating procedures.

   - Touch the [QC] icon in the [Menu] screen.
   - Select X-barM Setting.
   - Click [Execute] to perform X-barM Control, Click [Cancel] to deactivate.

3. Click [OK].X-barM control Error Review:

Laboratory staff will be using error sound alarm.

4. Activating / deactivating X-barM Control
   - Touch the [QC] icon in the [Menu] screen.
   - Select X-barM Setting.
   - Click [Execute] to perform X-barM Control, Click [Cancel] to deactivate.
   - Click [OK].

VI. OPERATING PROCEDURE

A. Start-Up Procedure

1. Checks prior to turning on:
   a. Visual inspections of analyzer / system / reagents
      1. If applicable, verify waste container is empty.
      2. Verify network / host connections are properly working.
      3. Verify sufficient reagent supply is nearby.

2. Turning ON the entire system
   a. Verify that all power switches for the device are in the ON position.
   b. Press the **Green** power button on the front of XN-L to power ON the entire System.

3. Log on to the XN-550/XN-530 IPU
   a. When the logon dialog box appears, enter username and password.

4. Analyzers self-checks
   a. XN-550/XN-530: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times).

XN-L Acceptable Background Counts	
Parameters	**Acceptable Limit**
WBC	0.10 x 10^3/ µL
RBC	0.02 x 10^6/µL
HGB	0.1 g/dL
PLT-I	10 x 10^3/ µL
WBC-BF*	0.001 x 10^3/ µL
RBC-BF*	0.003 x 10^6/ µL

**if applicable*

5. Analyze Quality Control Material

B. Patient Sample Processing

1. System Analysis (sampler analysis)
   a. Make sure the sampler cover (front) and sampler cover (manual unit) are closed.
   b. Make sure the button on the right edge of the control menu is set as sampler. When the mode is set to manual, press the mode switch.
   c. Make sure that either the left or right sampler adapter holder is in a state to be pulled out.

1. A sampler adapter holder can be pulled out when the sampler adapter status indicator LED is solid green or OFF.

d. Pull out the sampler adapter holder that you want to use.
e. Remove the sampler adapter.
f. Mix the sample.
g. Place the sample tube in the sampler adapter.
h. Touch Sampler on the right edge of the control menu.
i. Touch an item to set the condition.
j. Touch [OK].
k. Place the sampler adapter in the sampler adapter holder selected in the sampler settings box.
l. Push in the sampler adapter holder.
m. Press the sampler analysis start/stop switch.
n. On-Board rules engine will determine repeat or reflex testing.
o. Rack will run in reverse to perform repeat or reflex testing.
p. Remove the rack from the left sampler pool when analysis in completed.
q. Make smear if indicated.

2. Manual Analysis

a. Check the status of the analyzer. Confirm the analyzer is ready.
b. Make sure the button on right side of control menu is Manual. When it's set to Sampler, touch [Mode] in the control menu.
c. Select the Change Analysis Mode button on the control menu.
d. Select analysis mode.
   1. [Whole blood] is selected when whole blood is being analyzed
   2. [Low WBC] Select this to perform low WBC analysis on whole Blood *not available on the XN-530*
   3. [Pre-Dilution] select when running 1:7 diluted blood.
e. Select [OK]
f. Select Manual Analysis button on the control menu.
g. Input sample ID or use handheld barcode reader to scan sample ID.
   1. Patient information- Touch Input to enter patient ID.
   2. Query to Host-Specify whether or not the host is queried for the analysis order.
   3. Aspiration Sensor- Specify whether or not the aspiration sensor is used.
   4. Cap Open- Select this checkbox to perform micro sample analysis (analysis with the sample tube cap open.)
   5. Raised Bottom Tube- Assure appropriate adaptor in use – *See Instructions for Use Manual.*
   6. Dispense- Used to prepare diluted blood. Touch to start dispensing. CELLPACK DCL. For the dispensing procedure, see the following: (section 4.8 Preparing diluted blood with the diluent dispensing function in the XN-L Series Basic Operation Manual)
h. Select [OK]
i. Open the Sampler cover (manual unit).
j. Properly mix the specimen and place in the tube holder.
   1. If running micro sample, remove the cap using caution to avoid splattering.
k. Press the start switch on the analyzer.
   1. The tube holder will slide in and the sample will be aspirated
   2. When the analysis is complete, the tube holder slides out

l. Remove the sample, repeat steps for additional samples.
m. Review results in IPU to determine whether repeat or reflex testing is required. Rerun sample if required. Make smear if required.

VII. MAINTENANCE

A. XN-550/XN-530 Shutdown – performed daily

1. Confirm analyzer and sample units are ready.
2. Open Sample Cover (manual unit).
3. If any tubes remain in holder, remove.
4. Touch [Menu] on Toolbar.
5. Touch [Shutdown]. Touch [OK].
   a. XN-L on-board maintenance history will auto-populate Shutdown.
   b. IPU will automatically shut off at the conclusion.
   c. Press **Green** power button to restart IPU.

B. XN-550/XN-530 Routine Cleaning – performed weekly.

CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-L Series *Troubleshooting Manual* for detailed, illustrated procedures.

1. Confirm analyzers, sampler unit are at ready.
2. Touch the [Maintenance] Icon in the Menu screen.
3. Touch [Rinse Instrument].
4. Touch [Routine Cleaning].

   a. Open Sampler Cover (manual unit) and place CELLCLEAN AUTO in tube holder.
   b. Press start switch.
   c. XN-550/XN-530 on-board maintenance history will auto-populate Routine Cleaning.

CAUTION:

- Use 1 vial of CELLCLEAN AUTO for each instrument. Do not reuse CELLCLEAN AUTO that has previously been used.
- During Shutdown, other sample tubes are not accepted.

Maintenance performed on the XN-550/XN-530 will be automatically tracked in the maintenance history.

Refer to the XN-L Series Troubleshooting Manual for 'as needed' maintenance.

VIII. PROCEDURAL NOTES AND CALCULATIONS

A. If making a dilution of a patient specimen and running in XN-L Whole Blood or Body Fluid mode, multiply the parameters by the dilution factor. CELLPACK DCL should be

used as the diluent.

B. Do not use undiluted CELLPACK DST for dilution of patient samples.

C. If correcting the HGB or HCT due to interfering substances, recalculate and correct the affected indices:

1. MCHC = HGB / HCT x 100
2. MCH = HGB / RBC x 10
3. MCV = HCT / RBC x 10

D. Current on-board rules should be exported and saved to an external storage device each time a change is made. A printout of the rules should be inserted in the XN-L Series Application Manual.

E. **Do not** place samples on a mechanical rocker. Excessive mixing may alter white cell membranes resulting in false interpretive messages.

F. For troubleshooting specifics refer to the XN-L Series *Troubleshooting Manual*.

IX. REPORTING RESULTS

A. Adult and Pediatrics Reference Range: As per the attached Sysmex provided published reference range

X. REPORTING ABNORMAL RESULTS TO PHYSICIANS *(refer to the XN-L Flagging Guide: with L and high as per CliniSys built reference range* ***This may include criteria for specimen repeats if low WBC, recollection if QNS, hemolysis or grossly lipemic, pathology review, results to be called if critical as per the following table:***

Critical Hematology:

Test Name	Age	Critical Low	Critical High	Unit
Hemoglobin	0-7 weeks	$\leq$ 6.0	$\geq$24	g/dL
Hemoglobin	$\geq$ 7 weeks	$\leq$ 7.0	$\geq$21.0	g/dL
Hematocrit		$\leq$ 21	>65	
Leukocytes		2.0	>40	x 10^3/ µL
Absolute Neutrophil Count		$\leq$ 0.5		x 10^3/ µL
Platelets		$\leq$ 20	$\geq$1000	x 10^3/ µL
				x 10^3/ µL

XI. LIMITATIONS OF PROCEDURE

A. XN-L Series Manufacturer Stated Reportable Range

Parameter	Range	Units
WBC	0.04 – 440.0	x10^3/µL
RBC	0.02 – 8.60	x10^6/µL

HGB	0.1 – 26.0	g/dL
HCT	0.2 – 74.5	%
PLT	2 – 5000	$x10^3/\mu L$
RET%*	0.11 – 30	%
RET#*	0.0100 – 0.4576	$x10^6/\mu L$
IRF*	0.0 – 100.0	%

1. Parameters that exceed these limits are flagged with @ beside the result. The sample should be diluted, rerun and multiplied by the dilution factor.
2. CELLPACK DCL should be used as the diluent. *Do not use* CELLPACK DST for dilutions.
3. The laboratory director should define limits for accepting or rejecting.

B. Possible Sample Interferences (For additional information, refer to the analyzer *Instructions for Use*, *Flagging Guides, and Clinical Case Reports* located on the CRC).

1. Specimens must be free of clots and fibrin strands.
2. Marked changes in plasma constituents (e.g., low sodium, extremely elevated glucose) may cause cells to swell or shrink. The blood to anticoagulant ratio is important.
3. Red cell fragments, microcytic RBCs or white cell cytoplasmic fragments may interfere with automated platelet counts.
4. Cold agglutinins produce spurious macrocytosis, elevated MCHs MCHCs, falsely decreased RBC counts and HCTs. Rare warm agglutinins produce the same spurious results as a cold agglutinin.
5. Extremely elevated WBCs may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values.
6. Severely hemolyzed samples (*in vitro*) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
7. Giant platelets and clumped platelets may falsely elevate the WBC count and falsely decrease the platelet count. Platelet clumping and/or "platelet satellitism" can occur in specimens collected in EDTA. This may falsely elevate the WBC count and falsely decrease the platelet count. There are different methods for handling samples with platelet clumping or “platelet satellitism”.

   These methods include vortexing of the original sample and reanalyzing, recollection of the specimen, use of a different anticoagulant, introduction of an additive to the primary tube, or other steps. Laboratories should define and validate the method(s) used by their facility.
8. Abnormal paraproteins found in blood from patients with Multiple Myeloma can falsely increase the HGB. To correct HGB perform plasma replacement.
9. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK DCL.

10. Rocking specimen excessively, may affect the white cell membranes and cause false interpretive flags and messages.
11. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.

C. Flagging and Action Messages

Abnormal samples on the XN-L Series are identified using flagging systems to alert the user of a possible abnormality.

1. Suspect flags generate a message (e.g., Atypical Lymphocyte, WBC Abnormal Scattergram). Numerical results will display an asterisk and the specimen result will display as "Positive".
2. Analyzer generated error codes (e.g., DIFF channel errors). Error will display in both the Browser and Explorer screens.
3. User defined flags (e.g., leukocytosis, anisocytosis). These flags are programmable by the customer in the settings menu. When threshold limits are exceeded, a message appears, and the specimen result will display as "Positive".
4. Action Messages - The results are displayed in the Browser Screen.

   Refer to the Sysmex XN-L Series Automated Hematology Systems Flagging Interpretation Guide for additional information on flagging

XII. REFERENCES

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sysmex

CE

IVD

Package Insert Update

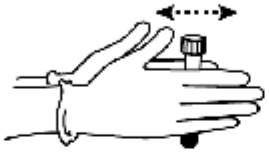
REF 213484, 213485, 213486, 213487, 213488, 213489

EN

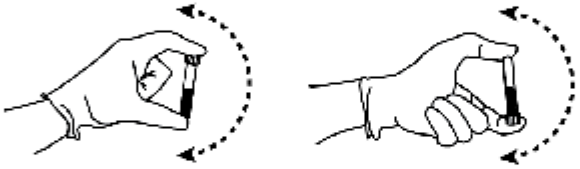
XN CHECK

Reagent preparation

1. Remove the vial from the refrigerator and equilibrate to room temperature (15-30°C) for 15 minutes before use.
2. Roll each vial between the palms of your hands for 15 seconds.



3. Holding the vial by the ends between the thumb and finger, invert the vial 20 times end-to-end using a very quick turning motion of your wrist during mixing (for more details please have a look onto the accompanying video on the CD Rom or USB stick).



4. Analyze the QC reagent in the instrument according to the Instructions for Use. The pierceable septum in the vial cap allows sampler analysis.
5. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
6. Return to refrigerator (2-8°C) storage.

Steps 1-6 must be repeated upon removing the sample from the refrigerator for the entire open-vial time period regardless of the method of analysis (open tube, cap piercing, auto sample or manual sample).

Manufacturer

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