**SUBJECT: SYSMEX XN-550 PROTOCOL**

1. **PRINCIPLE**

The Sysmex XN-550 is a multi-parameter quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 27\* whole blood 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 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%, RETIC%\*, RET-HE\*, IRF%\*.

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

***\*Depending upon activated licenses: applicable to Analyzer A (serial no. 26347)***

**II. SPECIMEN REQUIRMENTS**

* 1. **Required specimen**
     1. Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.
     2. Sodium Citrate may be used when EDTA platelet clumping or platelet satellitism is noted on the EDTA specimen. Use Sodium Citrate results for platelet counts and WBC counts. Multiply instrument PLT and WBC result by 1.1 to correct for anticoagulant dilution. Refer to policy Hemo-306.
  2. **Specimen volumes required**
     1. Optimal draw is a tube filled to capacity. Refer to collection tube manufacturer’s data for specific information on tube minimum and maximum fill volumes.

2. Best practice is to draw at least 1 ml in a regular tube and 250 μL in a microtainer tube.

3. The minimum volumes stated below are those required for appropriate

sampling by the analyzer. (The aspiration volume is 25 μL.)

a. Sampler analysis mode

1. Regular tube – 1 mL

b. Manual analysis whole blood mode

1. Closed regular tube – 1 mL

2. Open regular tube – 300 μL

3. Open microtainer – 100 μL

* 1. **Unacceptable specimens**

1. Specimens will be checked visually for obvious clots prior to sampling by the analyzer. Microsamples will be checked with a clean wooden applicator stick as well as any suspicious vacutainer tubes.

2. Unacceptable specimens including those listed below must be redrawn:

* Those containing fibrin or clots
* Excessive platelet clumping
* Substandard mixing or collection
* Expired or improperly stored collection tubes
* Improperly filled tubes
* Specimens drawn above an IV line
  1. **Characteristics that may affect test results**:
* Lipemia
* Icterus
* Gross Hemolysis
* Cold agglutinins
  1. **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. Stored at 4°C, EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability.
     3. Allow refrigerated samples to come to room temperature and mix well before analysis.

a. Best practice, upon removal from refrigerated storage, is to hand mix by inversion 20 times, allow to warm to room temperature for a minimum of 30 minutes and then hand mix by inversion 20 times prior to 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.

1. **SUPPLIES & REAGENTS**

**A. Supplies**

* + 1. Test tubes
    2. CELLCLEAN® AUTO
    3. Sysmex reagents
    4. Commercial Quality Controls: XN-L CHECKTM
  1. **Sysmex Reagents**
     1. Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-550 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 DFL\* 60 Days (2 x 1.5L)

SULFOLYSER™ 60 Days (2 x 1.5L)

Lysercell™ WDF 90 Days (5L)

Fluorocell™ WDF 90 Days (2 x 42mL)

Fluorocell RET\* 90 Days (2 x 12mL)

CellClean Auto Single Use Vial

**\**Dependent upon activated license: applicable to Analyzer A (serial no. 26347)***

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

CELLPACK DCL Storage

1. Store at 2o-35oC away from direct sunlight.
2. If frozen, thaw and mix thoroughly before using. Allow bubbles to dissipate before use.
3. 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

1. Unopened, stable until expiration date printed on the container.
2. Opened, stable for 60 days.

CELLPACK DCL 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 DCL does not have ingredients with those characteristics.

* + 1. **CELLPACK DFL (DFL)**\*: Whole blood diluent for use in hematology analyzers; used in combination with Fluorocell™ RET for the analysis of reticulocytes by flow Cytometry method using a semiconductor laser.

CELLPACK DFL Storage

1. Store at 2o-35oC away from direct sunlight.
2. Do not use the reagent if it is suspected to have frozen.
3. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

CELLPACK DFL Stability

1. Unopened, stable until expiration date printed on the container.
2. Opened, stable for 60 Days for 1.5L

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.

**\**Dependent upon activated license: applicable to Analyzer A (serial no. 26347)***

* 1. **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

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

SULFOLYSER Stability

1. Unopened, stable until expiration date printed on the container.
2. 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.

* + 1. **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

1. Store at 2o-35oC away from direct sunlight.
2. Use at an environmental temperature (15o-35oC).
3. Do not use the reagent if it is suspected to have frozen.
4. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

Lysercell WDF Stability

1. Unopened, stable until expiration date printed on the container.
2. 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.

* 1. **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

1. Store at 2o-35oC in a dark place.
2. Do not use the reagent if it is suspected to have frozen.

Fluorocell WDF Stability

1. Unopened, stable until expiration date printed on the container.
2. 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.

* + 1. **Fluorocell RET**\*: Used to stain the reticulocytes in diluted blood samples for the assay of reticulocyte count, reticulocyte percent in blood.

Fluorocell RET Storage

1. Store at 2o-35oC in a dark place.
2. Do not use the reagent if it is suspected to have frozen.

Fluorocell RET Stability

1. Unopened, stable until expiration date printed on the container.
2. 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.

**\**Dependent upon activated license: applicable to Analyzer A (serial no. 26347)***

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

CELLCLEAN AUTO Storage

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

CELLCLEAN AUTO Stability

1. 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.

* 1. **Commercial Quality Control Material for XN-550 analyzers**
     1. **XN-L CHECK**

1. Manufactured by Streck, available as a tri-level package.
2. Whole blood commercial control used to monitor performance of all XN-550 analyzers.
3. Formulation
   1. 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.
4. Storage
   1. Store vials at 2-8oC.
   2. Do not freeze or expose to excessive heat.
5. Stability
   1. Unopened and properly stored, XN-L CHECK is stable until the expiration date printed on the unopened vial.
   2. Open vial stability is 15 days for XN-L 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 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 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.

**H. Calibrators**

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

XN CAL Storage

* 1. Store the calibrator in a dark refrigerator at 2o-8oC.

XN CAL Stability

* + - 1. Unopened and properly stored, XN CAL is stable until the expiration date printed on the unopened vial.
  1. 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.

* 1. **XN-550 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
        1. Touch the name of the reagent to be replaced.
        2. 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 barcode 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 and out.

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.

* + 1. Replacing Dye
       1. Display the [Reagent Replacement] dialog box.
       2. Prepare the new reagent cartridge.
          1. Confirm the reagent has not expired.
       3. Pull out the dye holder.
       4. Slowly remove the dye cover, taking care that dye does not drip.
       5. Remove the entire dye holder.
          1. When the dye holder is removed, a [Help] dialog box appears in the IPU screen.
       6. Remove the old reagent cartridge from its holder.
       7. 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.
       8. Place the dye cover.
          1. Place into dye holder.
          2. The ID of the new reagent is read automatically and the information is registered.
       9. 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.

1. **PRECISION and CALIBRATION**

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, which include: Pipettor Assembly, Flow Cytometry Module, RBC Detector Assembly, and Hemoglobin Detector Assembly
* 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.

**BeyondCare Quality Monitor for Hematology (BCQM*h*)**

***Calibration and calibration verification processes:***

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 (see below) as defined by the service contract. The BCQM*h* Calibration History tab also documents calibration events.

A Continuous Calibration Verification (CCV) report will be generated at least every 6 months.

**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.

1. **QUALITY CONTROL**

***QC Process utilizing the BeyondCare Quality Monitor (BCQMh)***

Quality control is performed in order to monitor an analyzer’s performance over time. XN-L CHECK is the material used to monitor the performance of the XN-550 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 in the Activity Log. *(Refer to the BeyondCare Quality Monitor IFU for full details.)*

**NOTE:** LIS QC is there only as a time out reminder. Typing “OK” into the LIS indicates that the QC was completed for that shift. It is the technologist running the instrument to maintain that the proper levels per shift where indeed done and reviewed on the Sysmex XN-550.

**WARNING: POTENTIALLY INFECTIOUS MATERIAL.**

The human blood used in XN-L CHECK 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.

**A. XN-L CHECK Commercial Controls Instructions for Use**

1. Remove vials from the refrigerator and allow them to come to room temperature (18-25oC), 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.

**B. Frequency of Control use and review**

1st shift - run control levels: \_1 & 2\_

2nd shift - run control levels: \_1 & 3\_

3rd shift - run control levels: \_2 & 3\_

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

* Insight IQAP - monthly

*T****he supervisor reviews the BCQMh reports periodically:***

* Exception Report
* Summary Report
* Continuous Calibration Verification Certificate
* Calibration Certificates (every calibration)
* Detailed Daily Verification Report
* Parameter Report
* Traceability Report

**C. Registering and modifying a QC file – lot information input**

**Method: 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.

**D. 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.

**E. 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.

**F. Reviewing Quality Control Results in BeyondCare Quality Monitor**

The BCQM*h* program allows the user to customize QC analysis preferences for QC analysis into the program. The BCQM*h* Dashboard will notify the user as to when QC analysis is required and if that analysis falls within the acceptable limits. The dashboard colors are:

* **Green** – All control requirements have been met. Analyzer is Ready for patient

analysis.

* **Yellow** – Indicates additional action/information is required. Follow onscreen

steps for returning to analysis ready.

* **Red** – Indicates service is required due to a detected issue not resolved by

recommended corrective action.

* **Resolve –** Is activated if a QC error has been detected. Follow prompts to the

next course of action. The instructions button gives details on how to

perform the troubleshooting action.

* **QC is overdue –** End user needs to analyze QC since it exceeds the timeframe

determined by the preferences screen.

For a calendar view of whether the QC passed or failed, access the Summary report which will also display background status.

* + - P = Last 2 different levels of QC passed
    - F = QC failed
    - B = Background counts pass
    - X = Background counts failed
    - ? = Run QC
    - S = service event
    - Calibration (EBC)

***QC action plan for out of range commercial control products: Follow the BeyondCare Quality Monitor for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability.***

BeyondCare Quality Monitor will automatically not manage (exclude) a QC run if a corrective action has taken place and the same QC level is repeated and falls within the BeyondCare Quality Monitor specification limits. An “SM” (system managed) symbol will appear next to the raw data in the ***Insight*** report. No QC runs are ever deleted.

If the QC reviewer decides to manage (include data in calculations) or not manage (exclude data from calculations in the BeyondCare Quality Monitor application), log into ***Insight*** ([www.sysmex.com/Insight](http://www.sysmex.com/Insight)) and select Review QC data which will allow QC data management by the ***Insight*** user.

In the event that BeyondCare Quality Monitor for Hematology **(**BCQM*h*) is down or experiencing delays in processing times related to QC submissions:

a. Temporarily use the analyzer IPU QC files to determine the QC acceptability.

b. Once the processing time is back to normal, SNCS™ (Sysmex network communication system) will automatically sync the IPU QC files with Insight™ and BCQM*h*. The Summary report and DDV Reports will then reflect the sync of the IPU files.

**G. Recording and Storage of QC 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.

**H. Review of QC Data**

1. The following reports should be reviewed at regular intervals according to the laboratory’s policy: ***Insight*** *Report, Detailed Daily Verification Report, and Continuous Calibration Verification Certificate.*

* + 1. Once these reports have been reviewed through the BeyondCare Quality Monitor application, they can be accessed by going to Activity\_Reviewed Documents.
    2. Reports are archived for 2.5 years in BeyondCare Quality Monitor. Reports that are older than 2.5 years can be attained by contacting Sysmex Technical Assistance Center.

**I. Printing and saving QC Data**

1. Select [QC Files] icon and highlight file to output.

2. Select [QC Chart] icon.

3. Set Range of points to output by clicking [Range] and capturing the points with the cursors.

* + 1. Select [Output] to print the selected chart to either GP or LP.
    2. 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 to determine QC acceptability.

**J. *Insight*™ Quality Assurance Program (QAP)**

If your laboratory maintains an SNCS connection, the QC results will transmit automatically to ***Insight*** and BCQM*h* after each run. There is no need to batch upload the data to ***Insight*** andBCQM*h*.

The ***Insight*** account number is: 1111

The XN-550 serial nos. are: SN# 26347 (Analyzer A)

SN# 26353 (Analyzer B)

A Technical Supervisor (or designee) is responsible for saving the data to a USB memory device and submitting by due date in lieu of an SNCS connection.

1. Each XN-L CHECK lot has 3 data submission dates for the 100-day dated product.

2. Data may be managed in the XN-IPU and/or in ***Insight***. See ***Insight*** User Manuals.

3. Insert flash drive into USB port on the back of XN-L.

4. Select the QC file you want to output, click [File], [Output in Sysmex ***Insight***]. Save the file to the flash drive.

5. Repeat for each file needing ***Insight*** submission.

6. Properly eject the flash drive from the IPU.

7. At a networked PC, establish connection with the ***Insight*** program via [www.sysmex.com/us](http://www.sysmex.com/us) and submit the data. Contact the ***Insight*** team with questions at: 888-879-7639 (888-8SYSMEX).

**K. X-barM Moving Patient Averages**

The X-barM program will not be used as a quality control tool due to our low patient test volume (<100 samples/day). However, it will be left 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.

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

**VI. OPERATING PROCEDURE**

**A. Start-Up Procedure**

1. Checks prior to turning on:

* + - 1. Visual inspections of analyzer/system/reagents

1. Verify network/host connections are properly working.

2. Verify sufficient reagent supply is nearby.

* + 1. Turning ON the entire system
       1. Verify that all power switches for the device are in the ON position.
       2. Press the **Green** power button on the front of XN-L to power ON the entire System.
    2. Log on to the XN-550 IPU
       1. When the logon dialog box appears, enter user name and password.
    3. Analyzers self-checks
       1. XN-550: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times if exceeds limits).

|  |  |
| --- | --- |
| **XN-L Acceptable Background Counts** | |
| **Parameters** | **Acceptable Limit** |
| WBC | 0.10 x 103/ μL |
| RBC | 0.02 x 106/μL |
| HGB | 0.1 g/dL |
| PLT-I | 10 x 103/ μL |

* + 1. Analyze Quality Control Material

**B. Patient Sample Processing**

1. System Analysis (sampler analysis)

* + - 1. Make sure the sampler cover (front) and sampler cover (manual unit) are closed.
      2. 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.
      3. 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.

* + - 1. Pull out the sampler adapter holder that you want to use.
      2. Remove the sampler adapter.
      3. Mix the sample.
      4. Place the sample tube in the sampler adapter.
      5. Touch Sampler on the right edge of the control menu.
      6. Touch an item to set the condition.
      7. Touch [OK].
      8. Place the sampler adapter in the sampler adapter holder selected in the sampler settings box.
      9. Push in the sampler adapter holder.
      10. Press the sampler analysis start/stop switch.
      11. On-Board rules engine will determine repeat or reflex testing.
      12. Rack will run in reverse to perform repeat or reflex testing.
      13. Remove the rack from the left sampler pool when analysis in completed.
      14. 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] is selected to perform low WBC analysis on whole Blood.

**NOTE:** Use when WBC <0.5 or when dashes appear on the differential results.

3. [Pre-Dilution] is selected 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.

**C. Aspiration Sensor**

1. The aspiration sensor should be enabled in the Aspiration Sensor dialog box under Instrument Settings.

b. Not using the aspiration sensor may affect analysis results.

a. The aspiration sensor is not used in pre-dilution mode regardless of this setting.

3. The aspiration sensor should ONLY be disabled when analyzing extremely thin samples such as the following:

• Extremely thin blood, e.g., Hgb <4

• Whole blood dilutions when **not** using the pre-dilution mode

• Platelet poor plasma

4. Disabling the Aspiration Sensor

a. Turn off the aspiration sensor in the Manual Analysis dialog box.

b. Analyze the sample in the manual mode.

**NOTE:** Be sure to enable the aspiration sensor prior to testing subsequent samples in manual mode.

**VII. Maintenance**

**A. XN-550 Shutdown – performed daily**

1. Confirm analyzer and sample unit are at 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 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 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.

**C. Other Maintenance – As Needed**

*Refer to the XN-L Series Troubleshooting Manual for ‘as needed’ maintenance.*

**•** Replace the Air Pump – every 30,000 analyses, or once every 2 years

**•** Replace the Piercer – when piercer operation count exceeds 1200,000

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

**VIII**. **PROCEDURAL NOTES AND CALCULATIONS**

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

B. 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

C. Nucleated RBC's on peripheral blood smear:

1. Determine the number of NRBC/100 WBC either by scan or manual diff.

2.The LIS will automatically correct the WBC when the NRBC > 5 per 100 WBC.

**Corrected WBC = XN-550 WBC count x 100**

**100 + NRBC**

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 Reference Range (>12yr):

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Reference Range** | **Parameter** | **Reference Range** |
| WBC | 3.7-10.8 x103/uL | NEUT# | 1.6-7.7 x103/uL |
| RBC | male:      4.31-5.90 x106/uL | LYMPH# | 0.8-3.5 x103/uL |
|  | female:   3.97-5.19 x106/uL | MONO# | 0.3-0.8 x103/uL |
| HGB | male:      13.7-16.9 g/dL | EO# | 0.0-0.4 x103/uL |
|  | female:  12.0-15.7 g/dL | BASO# | 0.0-0.1 x103/uL |
| HCT | male:      39.9- 50.2 % | IG# | 0.00-0.03 x103/uL |
|  | female:   36.6- 46.7 % |  |  |
| MCV | 80.0-99.0 fL |  |  |
| MCH | 26.5-33.5 pg |  |  |
| MCHC | 30.9-35.6 g/dL |  |  |
| RDW-CV | 11.6-15.0 % |  |  |
| RDW-SD | 36.4-50.8 fL |  |  |
| MPV | 8.6-13.0 fL |  |  |
| PLT | 135-402 x103/uL |  |  |
|  |  |  |  |
|  |  | RET%\* | 0.5-2.6 % |
|  |  | RET#\* | 0.02-0.10 x106/uL |
|  |  | IRF\* | 0.3-17.1 % |
|  |  | RET-H*e\** | 24.1-35.8 pg |

***\*Dependent upon activated licenses: applicable to Analyzer A (serial no. 26347)***

B. Pediatric Reference Range:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Age** | **Parameter** | **Reference Range** | **Parameter** | **Reference Range** |
| 0-5day | WBC | 9.1-34.0 x103/uL | NEUT# | 6.0-23.5 x103/uL |
| 6day - <2yr |  | 5.9-16.7 x103/uL |  | 1.5-8.5 x103/uL |
| 2 - <12yr |  | 4.5-13.5 x103/uL |  | 1.5-8.0 x103/uL |
| 0-5day | RBC | 4.10-6.70 x106/uL | LYMPH# | 2.5-10.5 x103/uL |
| 6day - <2yr |  | 3.80-5.40 x106/uL |  | 1.8-9.0 x103/uL |
| 2 - <12yr |  | 4.00-5.30 x106/uL |  | 1.5-7.0 x103/uL |
| 0-5day | HGB | 15.0-24.0 g/dL | MONO# | 0.0-2.2 x103/uL |
| 6day - <2yr |  | 10.5-14.0 g/dL |  | 0.0-2.2 x103/uL |
| 2 - <12yr |  | 11.5-15.5 g/dL |  | 0.0-1.0 x103/uL |
| 0-5day | HCT | 44.0-70.0 % | EO# | 0.0-1.2 x103/uL |
| 6day - <2yr |  | 32.0-42.0 % |  | 0.0-1.2 x103/uL |
| 2 - <12yr |  | 35.0-45.0 % |  | 0.0-0.7 x103/uL |
| 0-5day | MCV | 100.0-120.0 fL | BASO# | 0.0-0.1 x103/uL |
| 6day - <2yr |  | 72.0-95.0 fL |  | 0.0-0.1 x103/uL |
| 2 - <12yr |  | 76.0-92.0 fL |  | 0.0-0.1 x103/uL |
| 0-5day | MCH | 33.0-39.0 pg |  |  |
| 6day - <2yr |  | 24.0-30.0 pg |  |  |
| 2 - <12yr |  | 25.0-33.0 pg |  |  |
| 0-5day | MCHC | 30.0-34.0 g/dL |  |  |
| 6day - <2yr |  | 30.0-36.0 g/dL |  |  |
| 2 - <12yr |  | 31.0-37.0 g/dL |  |  |
| 0-5day | RDW-CV | 13.0-18.0 % |  |  |
| 6day - <2yr |  | 11.5-16.0 % |  |  |
| 2 - <12yr |  | 11.5-15.0 % |  |  |
| All | RDW-SD | 36.4-50.8 fL |  |  |
| All | MPV | 8.6-13.0 fL |  |  |
| All | PLT | 135-402 x103/uL |  |  |
|  |  |  |  |  |
| 0-5day | RET%\* | 1.8-4.6 % |  |  |
| 6day - <2yr |  | 1.8-4.6 % |  |  |
| 2 - <12yr |  | 0.5-2.6 % |  |  |
| 0-5day | RET #\* | 0.15-0.22 x106/uL |  |  |
| All other |  | 0.02-0.10 x106/uL |  |  |
| All | IRF\* | 0.3-17.1 % |  |  |
| All | RET-H*e\** | 24.1-35.8 pg |  |  |

***\*Dependent upon activated licenses: applicable to Analyzer A (serial no. 26347)***

C. Critical Values

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Critical Low** | **Critical High** |
| WBC | < 2 thou/ul | >50 thou/ul |
| Hemoglobin | < 7 g/dL |  |
| Hematocrit | < 21 % |  |
| Platelets | <30,000 | >1,000,000 |

D. Acceptable Reporting Format:

1. Established and maintained by the LIS system

**X. REPORTING ABNORMAL RESULTS TO PHYSICIANS**

Refer to the following policies: nvml.jtdmh.Hemo-117 and nvml.jtdmh.Hemo-121

**XI. LIMITATIONS OF PROCEDURE**

1. **XN-L Series Manufacturer Stated Reportable Range**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Range** | **Units** |
| WBC | 0.04 – 440.0 | x103/μL |
| RBC | 0.02 – 8.60 | x106/μL |
| HGB | 0.1 – 26.0 | g/dL |
| HCT | 0.2 – 74.5 | % |
| PLT | 2 – 5000 | x103/μL |
| RET%\* | 0.11 – 30 | % |
| RET#\* | 0.0100 – 0.4576 | x106/μL |
| IRF\* | 0.0 – 100.0 | % |

**\**Dependent upon activated license: applicable to Analyzer A (serial no. 26347)***

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.

**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. An optical platelet may be performed to avoid this interference.
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.

1. Abnormal paraproteins found in blood from patients with Multiple Myeloma can falsely increase the HGB. To correct HGB perform plasma replacement.
2. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK DCL.
3. Rocking specimen excessively, may affect the white cell membranes and cause false interpretive flags and messages.
4. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.
5. **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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**Date: 08/28/23**