

## **Sysmex® XN-L 550™ Automated Hematology System**

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### **Principle**

The Sysmex XN-550 is a multi-parameter quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 23 whole blood diagnostic parameters. Examination of the numerical and/or morphological findings of the complete blood count by the physician are useful in the diagnosis of disease states such as anemias, leukemias, allergic reactions, viral, bacterial, and parasitic infections.

This device performs hematology analyses based on the hydrodynamically focused impedance measurement, the flow cytometry method (using a semiconductor laser) and the SLS-hemoglobin method.

The device 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.

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.

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### **Safety**

***Refer to the safety manual for general safety requirements.***

# **Sysmex® XN- L 550™ Automated Hematology System,** Continued

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## **Specimen Requirement**

- 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 13 x 75 tube filled to capacity
  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.
    - b. Open tube – 300 µL minimum sample volume.
    - c. Raised Bottom Tube – 250 µL minimum sample volume.
    - d. Open microtube – 100 µL minimum sample volume.
- C. Unacceptable specimens including those listed below must be redrawn:
  1. Those containing fibrin or clots
  2. Excessive platelet clumping
  3. Substandard mixing or collection
  4. Expired or improperly stored collection tubes
  5. Specimens contaminated with IV fluid
- D. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins.

## **Specimen Requirement, Continued**

- E. Stored Specimen Stability
    1. EDTA blood samples should be analyzed within 4 hours.
    2. If samples cannot be analyzed within 4 hours, store in a refrigerator at 2-8°C.
    3. Allow refrigerated samples to come to room temperature and mix well before analysis.
  - F. Do not place CBC and Diff samples on a mechanical rocker. Constant rocking may alter white cell membranes, resulting in false interpretive messages.
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# Sysmex<sup>®</sup> XN- L 550<sup>™</sup> Automated Hematology System, Continued

## Reagents

### A. Supplies

- 1) Lint-free lab wipes
- 2) Gauze
- 3) Test tubes
- 4) Pipettes
- 5) CELLCLEAN<sup>®</sup> AUTO
- 6) Sysmex reagents
- 7) Commercial controls; XN-L CHECK<sup>™</sup> or XN CHECK <sup>™</sup>

### B. 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.**

<u>XN-L REAGENTS</u>	<u>OPEN EXPIRATION</u>
CELLPACK <sup>™</sup> DCL	60 Days
SULFOLYSER <sup>™</sup>	60 Days (1.5L)
Lysercell <sup>™</sup> WDF	90 Days
Fluorocell <sup>™</sup> WDF	90 Days

### C. Diluents

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

#### CELLPACK DCL Storage/Stability

- a) Store at 2°-35°C away from direct sunlight.
- b) If frozen, thaw and mix thoroughly before using.

CELLPACK DCL is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace container.

# Sysmex® XN- L 550™ Automated Hematology System, Continued

## Reagents, Continued

- c) Unopened, it is stable until expiration date printed on the container.
- d) Opened, stable for 60 Days.

### 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/Stability

- a) Store at 1°-30°C away from direct sunlight.
  - b) Allow the container to equilibrate to environmental temperature (15-35°) prior to use.
  - c) Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.
  - d) Unopened, it is stable until expiration date printed on the container.
  - e) Opened, stable for 60 Days (1.5L) or 90 Days (5L).
- 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/Stability

- 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
- e) Unopened, it is stable until expiration date printed on the container.
- f) Opened, stable for 90 Days.

### 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/Stability

- a) Store at 2°-35°C in a dark place.
- b) Do not use the reagent if it is suspected to have frozen.
- c) Unopened, it is stable until expiration date printed on the container.
- d) Opened, stable for 90 Days

# Sysmex® XN- L 550™ Automated Hematology System, Continued

## Reagents, Continued

### F. Cleaning Agent

- 1) **CELLCLEAN AUTO:** Detergent for fully automated hematology analyzer. To be used as a strong alkaline detergent to remove lysing reagents, cellular residuals, and blood proteins remaining in the hydraulics of the analyzer on XN Series/XN-L Series automated hematology analyzers.  
CELLCLEAN AUTO Storage/Stability
  - a) Store at 1-30° C, away from direct sunlight.
  - b) Do not use the reagent if it is suspected to have frozen.
  - c) Unopened, it is stable until expiration date printed on the container.

## Reagent Replacement

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.

### 1. Replacing a new diluent / hemolytic agent

STEP	ACTION
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.
3	Using the hand-held reader, scan the reagent code on the new reagent container. <b>NOTE:</b> Scan Reagent Code 2 when available on the reagent container.
4	Remove the cap from the expired/empty container and carefully remove the spout.
5	Pull out the dispensing, set straight up.
6	Insert the dispensing set straight into the new reagent container and close the cap.
7	Select [Execute]. Reagent replacement starts. When complete, the dialog box closes automatically.

# Sysmex® XN- L 550™ Automated Hematology System,

Continued

**Reagent Replacement,**  
Continued

## 2. Replacing Dye

STEP	ACTION
1	Display the [Reagent Replacement] dialog box.
2	Prepare the new reagent cartridge. 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. 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 <ul style="list-style-type: none"> <li>• 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.</li> <li>• If the wrong reagent is installed, the analyzer beeps repeatedly and the Help dialog box appears in the IPU screen.</li> </ul>
8	Place the dye cover. <ol style="list-style-type: none"> <li>1. Place into dye holder.</li> <li>2. The ID of the new reagent is read automatically, and the information is registered.</li> </ol>
9	Close the dye holder. <ol style="list-style-type: none"> <li>1. Reagent replacement starts.</li> <li>2. When complete, the reagent replacement window closes automatically</li> </ol>

**Calibration & Precision**

For calibration procedure refer to Hematology Policy & Procedures XN-L 550 Calibration and Precision Procedure

**Quality Control**

For detailed QC procedure refer to Hematology Policy & Procedures XN-L 550 QC Procedure.

**Frequency of Control use and Review**

XN-L CHECK control levels: **ALL 3 levels** will be run daily on **ALL** (1<sup>st</sup> & 2<sup>nd</sup> shifts).

# Sysmex® XN- L 550™ Automated Hematology System,

Continued

**Quality Control,**  
Continued

**QC run time:**

**AM shift** – 0830 +/- 30 minutes (0800 to 0900)

**PM shift** – 1630 +/- 30 minutes (1600 to 1700)

**Note:** Since the XN only has one sample pathway, i.e. it only has one needle for aspiration, then it does not matter whether it is done in closed or open mode.

**Operating Procedure**

**A. Start-Up Procedure:**

STEP	ACTION																
1	Checks prior to turning on: <ul style="list-style-type: none"> <li>• Visual inspections of analyzer / system / reagents</li> <li>• If applicable, verify waste container is empty.</li> <li>• Verify network / host connections are properly working.</li> <li>• Verify sufficient reagent supply is nearby.</li> </ul>																
2	Turning ON the entire system <ul style="list-style-type: none"> <li>• Verify that all power switches for the device is in the ON position</li> <li>• Press the <b>Green</b> power button on the front of XN-L to power ON the entire system.</li> </ul>																
3	Log on to the XN-550 IPU When the logon dialog box appears, enter <b>admin</b> and password <b>m145m</b>																
4	Analyzers self-checks XN-550: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times). <table border="1" data-bbox="690 1444 1396 1816"> <thead> <tr> <th colspan="2">XN-L Acceptable Background Counts</th> </tr> <tr> <th>Parameters</th> <th>Acceptable Limit</th> </tr> </thead> <tbody> <tr> <td>WBC</td> <td>0.10 x 10<sup>3</sup>/ μL</td> </tr> <tr> <td>RBC</td> <td>0.02 x 10<sup>6</sup>/μL</td> </tr> <tr> <td>HGB</td> <td>0.1 g/dL</td> </tr> <tr> <td>PLT-I</td> <td>10 x 10<sup>3</sup>/ μL</td> </tr> <tr> <td>WBC-BF</td> <td>0.001 x 10<sup>3</sup>/ μL</td> </tr> <tr> <td>RBC-BF</td> <td>0.003 x 10<sup>6</sup>/ μL</td> </tr> </tbody> </table>	XN-L Acceptable Background Counts		Parameters	Acceptable Limit	WBC	0.10 x 10 <sup>3</sup> / μL	RBC	0.02 x 10 <sup>6</sup> /μL	HGB	0.1 g/dL	PLT-I	10 x 10 <sup>3</sup> / μL	WBC-BF	0.001 x 10 <sup>3</sup> / μL	RBC-BF	0.003 x 10 <sup>6</sup> / μL
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# Sysmex® XN- L 550™ Automated Hematology System, Continued

**Operating  
 Procedure,**  
 Continued

## A. Patient Sample Processing

### System Analysis (sampler analysis)

STEP	ACTION
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. <ul style="list-style-type: none"> <li>• A sampler adapter holder can be pulled out when the sampler adapter status indicator LED is solid green or OFF.</li> </ul>
4	Pull out the sampler adapter holder that you want to use. <ol style="list-style-type: none"> <li>a. Remove the sampler adapter.</li> <li>b. Mix the sample.</li> <li>c. Place the sample tube in the sampler adapter.</li> <li>d. Touch Sampler on the right edge of the control menu.</li> <li>e. Touch an item to set the condition.</li> <li>f. Touch [OK].</li> <li>g. Place the sampler adapter in the sampler adapter holder selected in the sampler settings box.</li> <li>h. Push in the sampler adapter holder.</li> </ol>
5	Press the sampler analysis start/stop switch <ul style="list-style-type: none"> <li>• On-Board rules engine will determine repeat or reflex testing</li> <li>• Rack will run in reverse to perform repeat or reflex testing.</li> </ul>
6	Remove the rack from the left sampler pool when analysis is completed.
7	Make smear if indicated.



# Sysmex® XN- L 550™ Automated Hematology System, Continued

**Operating Procedure,  
 Continued**

**Manual Analysis**

STEP	ACTION
1	Check the status of the analyzer. Confirm the analyzer is ready.
2	Make sure the button on right side of control menu is Manual. When it's set to Sampler, touch [Mode] in the control menu.
3	Select the Change Analysis Mode button on the control menu Select analysis mode: <ul style="list-style-type: none"> <li>• [Whole blood] is selected when whole blood is being analyzed</li> <li>• [Low WBC] Select this to perform low WBC analysis on whole blood</li> <li>• [Pre-Dilution] select when running 1:7 diluted blood.</li> <li>• [Body Fluid] selected for fluid analysis</li> </ul>
4	Select [OK]
5	Select Manual Analysis button on the control menu
6	Input sample ID or use handheld barcode reader to scan sample ID. <ul style="list-style-type: none"> <li>• <b>Patient information</b>- Touch Input to enter patient ID.</li> <li>• <b>Query to Host</b>-Specify whether or not the host is queried for the analysis order.</li> <li>• <b>Aspiration Sensor</b>- Specify whether or not the aspiration sensor is used.</li> <li>• <b>Cap Open</b>- Select this checkbox to perform micro sample analysis (analysis) with the sample tube cap open.)</li> <li>• <b>Raised Bottom Tube</b>- Assure appropriate adaptor in use – <i>See Instructions for Use Manual.</i></li> <li>• <b>Dispense</b>- Used to prepare diluted blood. Touch to start dispensing CELLPACK DCL. For the dispensing procedure, see the following. (section 4.8 diluted blood with the diluent dispensing function in the XN-L Series XN-550 Basic Operation Manual)</li> </ul>
7	Select [OK]
8	Open the Sampler cover (manual unit).

# Sysmex® XN- L 550™ Automated Hematology System,

Continued

## Operating Procedure, Continued

9	Properly mix the specimen and place in the tube holder. If running microtainer, remove the cap using caution to avoid splattering
10	Press the start switch on the analyzer <ul style="list-style-type: none"> <li>• The tube holder will slide in and the sample will be aspirated</li> <li>• When the analysis is complete, the tube holder slides out</li> </ul>
11	Remove the sample, repeat steps for additional samples
12	Review results in IPU to determine whether repeat or reflex testing is required. Rerun sample if required. Make smear if required.

## 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]. <ul style="list-style-type: none"> <li>• XN on-board maintenance history will auto-populate Shutdown.</li> <li>• IPU will automatically shut off at the conclusion.</li> </ul>
6	Press <b>Green</b> 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].
5	Open Sampler Cover (manual unit) and place CELLCLEAN AUTO in tube holder.
6	Press start switch <ul style="list-style-type: none"> <li>• XN-550 on-board maintenance history will auto-populate Routine Cleaning.</li> </ul>

## Sysmex® XN- L 550™ Automated Hematology System, Continued

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### Maintenance, **CAUTION:**

Continued

- 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 will be automatically tracked in the maintenance history. Refer to the XN-L Series *Troubleshooting Manual* for 'as needed' maintenance.

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### 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.
- 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.  $MCHC = HGB / HCT \times 100$
  2.  $MCH = HGB / RBC \times 10$
  3.  $MCV = HCT / RBC \times 10$
- D. Current on-board rules must be exported and saved on 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*.

# Sysmex® XN- L 550™ Automated Hematology System, Continued

## Limitations of Procedure

### A. XN-L Series Manufacturer Stated Reportable Range

Parameter	Range	Units
WBC	0.04-440.0	$\times 10^3/\mu\text{L}$
RBC	0.02-8.60	$\times 10^6/\mu\text{L}$
HGB	0-26.0	g/dL
HCT	0.2-75.0	%
PLT	1-5000	$\times 10^3/\mu\text{L}$

1. Parameters that exceed these limits are flagged with @ beside the result. The sample must be diluted, rerun and multiplied by the dilution factor.
2. Note the use of dilution for linearity on the patient report.

# Sysmex® XN- L 550™ Automated Hematology System, Continued

## Limitations of Procedure, Continued

### B. Possible Sample Interferences

(For additional information, reference 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 or adding amikacin to the original sample and reanalyzing. 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 WBC differential.
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.

## Sysmex® XN- L 550™ Automated Hematology System, Continued

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**

### Controlled Documents

The following controlled documents support this procedure.

Reference
1. Sysmex XN-L Series XN-550/XN-450/XN-350 Basic Operation (North American Edition), Sysmex Corporation, Kobe, Japan.
2. Sysmex XN-L Series XN-550/XN-450/XN-350 General Information (North American Edition), Sysmex Corporation, Kobe, Japan.
3. Sysmex XN-L Series XN-550/XN-450/XN-350 Troubleshooting (North American Edition), Sysmex Corporation, Kobe, Japan.
4. Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).
5. Sysmex Reagents of America Inc., Mundelein, IL. XN CAL, Hematology Calibrators: Calibrators for Sysmex Hematology XN-L Series Analyzers, package insert.
6. Sysmex America Inc., Lincolnshire, IL. XN-L CHECK Hematology Control for Sysmex XN-L Series Analyzers package insert.
7. Sysmex America Inc., Lincolnshire, IL. Sysmex <i>Insight</i> Participant Overview Guide.
8. Koepke, John. <i>Practical Laboratory Hematology</i> . Churchill Livingstone Inc. 1991 p. 24-25, 36-39.
9. Cornbleet J., <i>Spurious results from automated hematology cell counters</i> . <i>Lab Medicine</i> . 1983;8:509-514.
10. Sysmex Reagents of America, Inc. SDS sheets and reagent product inserts.

# Sysmex® XN- L 550™ Automated Hematology System, Continued

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12. Stewart, Charles and Koepke, John. <i>Basic Quality Assurance Practices for Clinical Laboratories</i> , Van Nostrand Reinhold, 1989, p 189.
13. Gulati GL, Asselta A, Chen C. <i>Using vortex to disaggregate platelet clumps</i> , Laboratory Medicine, 28:665, 1997.
14. Zhou X, Xiaoli W. <i>Amikacin Can Be Added to Blood to Reduce the Fall in Platelet Count</i> , American Journal of Clinical Pathology, 136:646-652, 2011.
15. Sysmex America Inc., Lincolnshire, IL. XN-L Applications Manual.
16. Sysmex America Inc., Lincolnshire, IL. BeyondCare <sup>SM</sup> Quality Monitor User Manual
17. Sysmex XN-L Series Automated Hematology Systems Flagging Interpretation Guide, Document Number: 1399-LSS, Rev 1, December 2017.
18. Reagent Unit RU-20 Instructions for Use. Sysmex Corporation, Kobe Japan.
19. CLSI document H56-A – Body Fluid Analysis for Cellular Composition; Approved

### Attachments

- |  |
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| A. XN-550_QuickGuide1231-CFL                 |
| B. XN-L Series Flagging Guide_1399-LSS__Rev2 |

