# Sysmex<sup>®</sup> XN-9000<sup>™</sup>Automated Hematology System

Principle	The Sysmex XN-9000 is an integrated system that incorporates hematology analytical modules as well as automated slidemaker/stainer(s).
	The analytical module is a quantitative automated hematology analyzer for <i>in vitro</i> diagnostic use in determining 31 whole blood diagnostic parameters and 7 body fluid 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.
	The analyzer performs hematology analysis according to the hydrodynamic focusing (DC Detection), flow cytometry method (semiconductor laser), and SLS-hemoglobin method.
	The device counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection. Hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin (HGB) is converted to SLS-hemoglobin and read photometrically.
	The white blood cell (WBC) count, differential (DIFF), reticulocytes (RET), nucleated red blood cells (NRBC) and fluorescent platelets (PLT-F) are all evaluated using flow cytometry with a semiconductor laser exploiting the differences in cell size, complexity and RNA / DNA content. Forward scattered light provides information on blood cell size and Lateral scattered light provides information on blood cell size of the nucleus. Lateral fluorescent light intensity increases as the concentration of the stain becomes higher. By measuring the intensity of the fluorescence emitted, information is obtained on the degree of blood cell staining. Fluorescent light is emitted in all directions. The XN detects the fluorescent light that is emitted sideways.
	The Sysmex SP-10 is a fully automated hematology slide preparation and staining system. Whole blood specimens are mixed and aspirated and a wedge type blood smear is prepared using hematocrit information from the Sysmex XN to determine optimum smearing criteria. The dried smear is automatically loaded into an individual slide cassette and is then advanced to the staining area. In the staining area, stain and buffer are dispensed into the cassette at operator-defined intervals.
	The system also provides a manual mode operation where pre-made smears may be added to be stained. The unit is self-monitoring and alarms when operation is interrupted.
	Slides prepared by the Sysmex SP-10 are used for differentiation and morphologic evaluation of cellular elements of whole blood.

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Safety	All specimens, reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance. Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01.	
Specimen	A. Required specimen	
Requirements	<ol> <li>Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.</li> </ol>	
	<ol> <li>Serous and synovial fluids should be collected in EDTA-2K anticoagulant.</li> </ol>	
	<ol> <li>The use of anticoagulant with CSF specimens is neither required nor recommended.</li> </ol>	
	B. Specimen volumes required	
	1. Optimal draw is a 12 x 75 mm 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	
	b. Open tube – 300 μL	
	c. Open microtube – 160 μL	
	<ol><li>Manual analysis body fluid mode</li></ol>	
	a. Closed tube – 1 mL	

- b. Open tube 300 µL
- c. Open microtube 160 µL
- 5. Manual analysis SP-10
  - a. Closed tube smear and staining 1 mL is optimal, 200  $\mu$ L is aspirated.
- C. Unacceptable specimens including those listed below must be redrawn:
  - 1. Clotted samples or those containing clots, fibrin strands, or platelet clumps. All specimens should be checked visually for obvious clots prior to sampling by the analyzer.
  - 2. Grossly hemolyzed samples
  - 3. Samples drawn above an IV line
- D. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins.
- E. Stored Specimen Stability
  - 1. Stored at 4-8°C, EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability.
  - 2. Sample stability at room temperature is 24 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours, which may be minimized by refrigeration.
  - 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.

#### Reagents

- 1) Deionized water
- 2) Gauze

A. Supplies

- 3) Test tubes
- 4) Plastic squeeze bottles
- 5) CELLCLEAN® AUTO
- 6) Sysmex reagents
- 7) Commercial controls; XN CHECK<sup>™</sup>, XN CHECK<sup>™</sup> BF
- 8) Alcohol prep pads, isopropyl. Used to clean SP-10 spreader glass
- 9) Microscope slides, frosted with rounded / clipped corners (76 x 26 mm; 0.9 – 1.2 mm thick)
- B. Sysmex Reagents
  - 1) Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-Series modules.
  - 2) All reagents are used at room temperature and are to be used within the manufacturer's expiration date on each container.
  - Record date received and date opened on container. All reagents are azide free and are intended for *in vitro* diagnostic use only. **Do not** ingest.

XN REAGENTS	OPEN EXPIRATION
CELLPACK DCL	60 Days
CELLPACK DST	60 Days
CELLPACK DFL	60 Days
SULFOLYSER	90 Days (5.0L)
Lysercell WNR	60 Days
Fluorocell WNR	90 Days
Lysercell WDF	90 Days
Fluorocell WDF	90 Days
Fluorocell RET	90 Days
Fluorocell PLT	90 Days
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## SP REAGENTS

Stain – Wright Stain: Harleco, Ref #740-85Buffer – pH 6.6 – 7.2: Sysmex Buffer Solution, Ref # ACC-SP5573Methyl Alcohol: Thermo Scientific, Ref # 9600-1CELLPACK DCL60 Days

- C. Diluents
  - 1) CELLPACK DCL: Whole blood diluent for use in hematology analyzers and for use as a rinsing agent for the spreader glass, sample pipette, and piercer on the SP-10.
  - 2) CELLPACK DST (DST): Concentrated diluent of reagent for use in hematology analyzers.
  - 3) CELLPACK DFL (DFL): Whole blood diluent for use in hematology analyzers; used in combination with Fluorocell<sup>™</sup> RET for the analysis of reticulocytes, or with Fluorocell PLT for the analysis of platelets by flow cytometry method using a semiconductor laser.

Reagents, continued	<ul> <li>D. Lysing Reagents <ol> <li>SULFOLYSER (SLS): Reagent for the automated determination of hemoglobin concentration of blood. Sulfolyser is a lysing reagent that releases the hemoglobin to be measured by the SLS hemoglobin method.</li> <li>Lysercell WNR: Reagent product to be combined and used with Fluorocell WNR. By hemolyzing red blood cells with Lysercell WNR and by differentiating white blood cells (non-basophil), basophils, and nucleated red blood cells with Lysercell WNR and Fluorocell WNR, the white blood cell count, basophil count, basophil percentage, nucleated red blood cell count, basophil count, basophil percentage are analyzed.</li> <li>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, immature granulocytes, lymphocytes, monocytes, and eosinophils are analyzed.</li> </ol> </li> </ul>	
	<ul> <li>E. Staining Reagents <ol> <li>Fluorocell WNR: Used to stain the nucleated cells in diluted and lysed blood samples for determination of white blood cell count, nucleated red blood cell count and basophil count in blood.</li> <li>Fluorocell WDF: Used to stain the leukocytes in diluted and lysed blood samples for determination of differential count in blood.</li> <li>Fluorocell RET: Used to stain the reticulocytes in diluted blood samples for the assay of reticulocyte count, reticulocyte percent in blood.</li> <li>Fluorocell PLT: Used to stain the platelets in diluted blood samples for the assay of platelet counts in blood.</li> </ol> </li> </ul>	
	F. Cleaning Agent CELLCLEAN AUTO: Detergent for fully automated hematology analyzers. To be used as a strong alkaline detergent to remove lysing reagents, cellular residuals, and blood proteins remaining in the hydraulics of the analyzer. For use as a cleaning fluid for the hematology analyzers and the SP-10.	
Reagent Replacement	When the reagent runs out during analysis, the analysis is paused and an error message appears in the analyzer area of the Control menu. Follow steps below:	
	Display the <b>[Reagent Replacement]</b> dialog box to replace the reagent. a. Select the help button on the control menu b. Select <b>[Execute].</b> Remaining Reagent Volume indicator appears.	

To replace a new diluent / hemolytic agent:

- a. Display the [Reagent Replacement] dialog box.
- b. Remove the cap from the new reagent container. Confirm the reagent has not expired.

Reagent Replacement, continued	<ul> <li>c. Input the reagent code (barcode) <ul> <li>Place the cursor in the reagent code field</li> <li>Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.</li> <li>Select [OK]</li> </ul> </li> <li>d. Remove the cap from the old reagent container.</li> <li>e. Pull out the dispensing set straight up.</li> <li>f. Insert the dispensing set straight into the new container.</li> <li>g. Close the cap.</li> <li>h. Select [Execute]. Reagent replacement starts. When complete, the dialog box closes automatically.</li> </ul>
	To replace CELLPACK DST with an RU-20: a. Display the RU-20 Maintenance menu b. Select <b>[Replace Reagent]</b>
	<ul> <li>c. Remove the cap from the new reagent container. Confirm that reagent has not expired.</li> </ul>
	<ul> <li>d. Input the reagent code (barcode)</li> <li>Place the cursor in the reagent code field</li> <li>Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.</li> <li>Select [OK].</li> </ul>
	e. Remove the cap from the old reagent container.

- f. Pull out the dispensing set straight up.
- g. Insert the dispensing set straight into the new container.
- h. Close the cap.
- i. Select **[Execute]**. Reagent replacement starts. When complete, the dialog box closes automatically.
- To replace dye:
  - a. Display the [Reagent Replacement] dialog box.
  - b. Prepare the new reagent cartridge. Confirm the reagent has not expired.
  - c. Open the top front cover.
  - d. Pull up the cover from the reagent that is to be replaced. A **Help** dialog box appears in the IPU screen.
  - e. Remove the old reagent cartridge from its holder.
  - f. Insert the new reagent cartridge into the holder.
    - 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.
    - If the wrong reagent is installed, the analyzer beeps repeatedly and the **Help** dialog box appears in the IPU screen.
  - g. Pull down the cover on the reagent until you hear a click. The **Help** dialog box closes automatically.
    - The ID of the new reagent is read automatically and the information is registered.
  - h. Close the top front cover. Reagent replacement starts. When complete, the reagent replacement window closes automatically.

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California Division – South	Procedures

Reagent Replacement.	SP-10 Reagent Replacement The following is a list of replacement me	gent Replacement	
continued	Message *DCL not filled	Reagent CELLPACK DCL	
	*Stain 1 not filled in Chamber 1	Stain	
	*Stain 1 not filled in Chamber 2	Stain	
	*Stain 2 not filled	2 <sup>nd</sup> stain (if using 2 stain method)	
	*Rinse water not filled (internal chamber not filled)	Deionized water	
	Replace Rinse water (external container empty)	Deionized water	
	Replace buffer	Buffer	
	Replace methanol	Methanol	
	* Reagents with internal chambers.	Other reagents use bottle sensors	
	<ul> <li>a. When a reagent container is employed displays. Press [OK] to silence the b. Press [Help] icon and follow the c. When replacing a reagent with an the action message and reset. For error clears when the reagent is not dependent on a contaminated surface sensor on a contaminated surface for the sensor on the sensor on a contaminated surface for the sensor on the se</li></ul>	bty, an alarm sounds and a dialogue box ne alarm and close the dialogue box. corrective action message. In internal chamber, press <b>[OK]</b> to clear or reagents with bottle sensors, the replaced or filled. Innique. Avoid placing spout kit or ne.	
Calibration & Precision	For calibration procedure refer to Hemat Calibration and Precision Procedure.	ology Policy & Procedures, 02-0011 XN	
Quality Control	For detailed QC procedure refer to Hem XN QC Procedure.	atology Policy & Procedures, 02-0010	
	Frequency of Control use and review		
	XN CHECK control levels: ALL 3 levels shifts and ALL XNs.	will be run daily on <b>ALL</b> (1 <sup>st</sup> , 2 <sup>nd</sup> & 3 <sup>rd</sup> )	
	XN CHECK BF control levels: All 2 leve shifts in the Manual BF mode. Body Flu XN 3. And XN 2 will be the backup.	Is will be run on ALL (1 <sup>st</sup> , 2 <sup>nd</sup> & 3 <sup>rd</sup> ) id analysis will be done primarily on	

SP-10 QC slide will be evaluated daily on the 1st shift

## QC run time:

AM shift - 0830 +/- 30 minutes (0800 to 0900) PM shift - 1630 +/- 30 minutes (1600 to 1700) Night shift - 0030 +/- 30 minutes (0000 to 0100)

**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:

- 1. Checks prior to turning on
  - a. Visual inspections of analyzer / system / reagents
    - a. Place completed samples into final storage area for the lab.
    - b. Gather and relocate all empty racks to designated processing or sample loading area.
    - c. Verify waste container is empty.
    - d. Verify network / host connections are properly working.
    - e. Ensure that the towers (slide supply cassettes) have sufficient slides. Fill with glass slides.
      - Remove the tower to be filled.
      - Remove the metal insert from the end of the tower.
      - Fan the slides to prevent them from adhering to each other and place them with the frosted end up and towards the open end of the tower.
      - Replace the metal insert and replace the tower with the frosted end of the slides towards the back of the analyzer.
    - f. Fill the cassette supply table with clean, dry single cassettes. The Sysmex logo should be forward and the notch at the bottom <u>must</u> be away from you (or to the left). The supply table holds up to 100 cassettes. A minimum of 8 cassettes are required for start-up.
- 2. Turning **ON** the entire system
  - a. Verify that all power switches for each device are in the ON position
  - b. Press the green master switch on the BT to power **ON** the entire system.
- 3. Log on to the XN-IPU
  - a. To logon, enter: user name: XN and password: XN
- 4. Analyzers and SP-10 self-checks
  - a. XN: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times)

XN Acceptable Background Counts	
Parameters	Acceptable Limit
WBC-N	0.10 x 10³/ μL
WBC-D	0.10 x 10³/ μL
RBC	0.02 x 106/µL
HGB	0.1 g/dL
PLT-I	10 x 10 <sup>3</sup> / µL
PLT-F	3 x 10³/ μL

- b. SP-10: System check to evaluate internal stored data files; shutdown check to determine whether shutdown was performed properly, a mechanical initialization sequence.
- 5. Perform QC for all XN modules.

# **B.** Patient Sample Processing:

1. System Analysis (sampler analysis)

Step	Action
1	Make sure the analyzer and the sampler are in <b>READY</b> state.
2	Check that tube holder has retracted into the analyzer, press mode
	button if necessary.
3	Place barcoded sample(s) in rack(s) in the feeder.
4	Rack(s) will be automatically pushed forward and routed to BT.
5	Samples will run, results will be displayed in the IPU.
6	Sysmex WAM will determine repeat or reflex testing.
7	Rack will run in reverse to perform repeat or reflex testing on the same
	XN.
8	• If smear is required, rack will be transported to SP-10 via feeder line
	and samples will be aspirated by SP-10.
	If no smears are required, rack will be transported via collector line
	to the collector and will not be routed to SP-10.
9	Remove the rack(s) when analysis in completed.

# 2. Manual Analysis

Step	Action	
1	Check the Status indicator LED on the analyzer to confirm analyzer is	
	in <b>READY</b> state.	
2	Press the mode switch to eject the tube holder.	
3	Select the Change Analysis Mode button on the control menu.	
4	Select analysis mode:	
	[Whole blood] is selected when whole blood is being analyzed [Low WBC] Select this to perform low WBC analysis on whole blood [Pre-Dilution] select when running 1:7 pre-diluted blood	
5	Select [OK]	
6	Properly mix the specimen and place in the tube holder.	
	<ul> <li>If running microtainer, remove the cap using caution to avoid</li> </ul>	
	splattering.	
7	Press the start switch on the analyzer.	
	<ul> <li>The tube holder will slide in and the sample will be aspirated</li> </ul>	
	<ul> <li>When the analysis is complete, the tube holder slides out</li> </ul>	
8	Remove the sample, repeat steps for additional samples.	
9	Review results in IPU to determine whether repeat or reflex testing is	
	required. Rerun sample if required. Make smear if required.	

## 3. Body Fluid Analysis

Step	Action
1	Check the Status indicator LED on the analyzer to confirm analyzer is
	in <b>READY</b> state.
2	Press the mode switch to eject the tube holder.
3	Select the Change Analysis Mode button on the control menu.

4	Select [Body Fluid].					
	Note: The analyzer will automatically perform a background check up					
	to three times.					
5	Select [OK]					
6	Properly mix the specimen and place in the tube holder.					
7	Press the start switch on the analyzer.					
	<ul> <li>The tube holder will slide in and the sample will be aspirated</li> </ul>					
	<ul> <li>When the analysis is complete, the tube holder slides out</li> </ul>					
8	Remove the sample, repeat steps for additional samples.					
9	Perform background check prior to running additional QC samples by					
	selecting [Auto Rinse] from the analyzer menu button.					
10	Return analyzer to Whole Blood mode prior to running whole blood					
	samples by pressing the mode switch button.					

4. SP-10 Manual Mode – Smear and Stain

Step	Action				
1	Press [Conv. Int.] on the SP-10 main menu screen.				
2	Press [Interrupt].				
3	Select [Return].				
4	Select [Manual] on the SP-10 main menu screen.				
5	Op Mode is set to [Smr + Sta], Smpl. Tube is set to [Closed]				
6	Input Specimen information, Sample ID, HCT, select number of slides				
	to be made.				
7	Thoroughly mix the sample and place in 10 <sup>th</sup> rack position.				
8	Place the rack so that the sample aligns with the tube gripper and that				
	the left end of the rack fits the label on the sampler.				
9	Select [Start]				
	Analysis will begin				
	<ul> <li>When the tube is returned to the rack, remove the rack</li> </ul>				
10	Press [Return], [Conv. Int.], [Stop Int.].				

5. SP-10 Manual Mode – Stain Only

Step	Action					
1	Select [Manual] mode.					
2	Select [Op. Mode], [Stain]. Do not proceed until [START] button is					
	green.					
3	Place labeled, unstained blood films into cassettes at the front of the					
	cassette supply table on the right side of the analyzer. If multiple slides					
	are to be stained, place them in consecutive cassettes.					
4	Press [Start].					
5	The cassettes will be fed to the stain table and the smears will be					
	stained. An empty cassette will follow to indicate the end of the run.					

Operating	6. SP-10 Smear Only – No staining occurs
Procedure,	
continued	To use Smear Only in Manual Closed Mode

Step	Action			
1	Press [Conv. Int.] on the SP-10 main menu screen.			
2	Press [Interrupt].			
3	Select [Return].			
4	Select [Manual] on the SP-10 main menu screen.			
5	Op Mode is set to [Smear], Smpl. Tube is set to [Closed].			
6	Input Specimen information, Sample ID, HCT, select number of slides			
	to be made.			
7	Thoroughly mix the sample and place in 10 <sup>th</sup> rack position.			
8	Place the rack so that the sample aligns with the tube gripper and that			
	the left end of the rack fits the label on the sampler.			
9	Select [Start]			
	Analysis will begin			
	<ul> <li>When the tube is returned to the rack, remove the rack</li> </ul>			
10	Press [Return] [Conv. Int.] [Stop Int.].			
11	Remove the rack when sampling is complete.			

Return Setting to SMEAR + STAINING:

Press [Settings], [Select], [Cond.], [Mode], [Smr + Sta.]. Press [RETURN] and [YES].

## C. Shutdown – Performed Daily

CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-9000 *Instructions for Use* for detailed, illustrated procedures.

Step	Action			
1	Confirm analyzers, conveyors, and SP-10 are at ready.			
2	Confirm tube holders are retracted into the analyzers.			
3	Obtain empty blue maintenance rack labeled SRRA00. Place one tube			
	of CELLCLEAN AUTO in the rack for each module or SP-10 requiring			
	maintenance beginning with position 10 and load backwards.			
4	Place rack on feeder unit, sampler unit will auto-start.			
5	XN on-board maintenance history will auto-populate.			
6	Document shutdown on the SP maintenance log.			

## D. Maintenance

Document all maintenance procedures on the appropriate log sheet for the SP-10. Maintenance performed on the XN will be automatically tracked in the maintenance history.

Operating	1. SP-10
Procedure,	a. Daily
continued	<ol> <li>Clean Spreader Glass: Power must be on to perform this maintenance – may be performed prior to Shutdown, or after Start-</li> </ol>
	up.
	a. Press [Maint.] on the main screen. (Maintenance button is not available during routine operation)
	h Press [Snreader Glass] and the "Snreader Glass Replace"
	screen displays
	c. Press <b>[OK]</b> to move the smear unit forward.
	d. Remove the left tower for easier access to the spreader glass.
	e. Wipe the spreader in one direction with an alcohol prep pad.
	f. Replace the tower so that the frosted end of the slides are
	towards the back of the analyzer.
	g. Press <b>[OK]</b> to return the smear unit to the nome position.
	I. Press [OK] to reset the spreader glass cycle counter of
	i Press [RETIIRN]
	2 Clean Single Cassettes
	a. Place cassettes in a bin with open end up.
	b. Pour methanol over the cassettes, filling them.
	c. Swish the methanol and pour off into designated container for
	reuse.
	d. Invert cleaned cassettes on absorbent material to dry.
	<b>Note:</b> Methanol may be reused for cleaning cassettes up to three (3) times.
	b. Weekly
	1. Perform Shutdown 2 (Weekly)
	a. Press [SHUTDOWN] on the main screen.
	b. Press [Shutdown 2] (Weekly).
	c. The shutdown screen displays the number of cassettes and
	amount of methanol required for the shutdown process. Ensure
	d Place a tube of CELLCLEAN ALITO in position 10 of a Sysmex
	rack.
	e. Place the rack so that the tube is lined up with tube gripper.
	f. Press [OK].
	g. When the process completes, the SP-10 turns off automatically.
	h. To restart the SP-10, press the green button on the right side.
	2. Clean DI water/Buffer containers
	<ol> <li>a. If re-usable containers for deionized water and/or buffer are</li> </ol>
	used, empty weekly.
	b. Rinse with methanol and allow to dry.
	C. Fill with fresh deionized water or buffer.
	3. As Needed Maintenance
	Refer to the XN-9000 Instructions for Use for detailed and illustrated
	instructions for performing as needed maintenance.

Procedural Notes and Calculations	<ul><li>A. If making a dilution of a patient specimen and running in XN Whole Blood mode, multiply the parameters by the dilution factor.</li><li>B. If correcting the HGB or HCT due to interfering substances, recalculate and correct the affected indices:</li></ul>				
	<ol> <li>MCHC = HGB / HCT x 100</li> <li>MCH = HGB / RBC x 10</li> <li>MCV = HCT / RBC x 10</li> </ol>				
	C. Use the Help function on the SP-10 when errors and messages display. Use the error icon on the XN to display help menu.				
	D. While slides are being processed on the SP smear table, the START key may not be available for manual mode processing.				
	E. During normal processing of slides on the SP-10, Maint., Settings, and Shutdown functions are not available.				
	F. Current settings for XN and SP-10 should be recorded and maintained in the XN-Series Resource Manual and the SP-Series Implementation Manual.				
	G. 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-Series Resource Manual each time a change is made.				
	H. <b>Do not</b> place samples on a mechanical rocker. Excessive mixing may alter white cell membranes resulting in false interpretive messages.				
	I. For troubleshooting specifics refer to the Sysmex XN-9000 Instructions for Use.				

Limitations of	A. XN-Series Manufacturer Stated Linearity	
Procedure		

Parameter	Range	Units
WBC	0-440.0	x10³/µL
RBC	0-8.60	x10 <sup>6</sup> /µL
HGB	0-26.0	g/dL
HCT	0-75.0	%
PLT, PLT-F	0-5000	x10³/µL
RET%	0-30	%
NRBC%	0-600	/100 WBC

- 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.
- B. Possible Sample Interferences
  - 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 RBC's, or white cell cytoplasmic fragments may interfere with automated platelet counts. A fluorescent platelet may be performed to avoid this interference.
  - 4. Cold agglutinins produce spurious macrocytosis, elevated MCH's & MCHC's, falsely decreased RBC counts and HCT's. 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. Abnormal paraproteins found in Multiple Myeloma patients can falsely increase the HGB. To correct HGB perform plasma replacement.
  - 8. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK.
  - 9. 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.
  - 10. Rocking specimen excessively, may affect the WBC differential.
  - 11. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.

References:	<ol> <li>Sysmex XN-9000 Instructions for Use (North American Edition), Sysmex Corporation, Kobe, Japan.</li> </ol>
	2. Sysmex XN series Administrator's Guide (North American Edition), Sysmex Corporation, Kobe, Japan
	<ol> <li>Sysmex SP-10 Instructions for Use (North American Edition), Sysmex Corporation, Kobe, Japan.</li> </ol>
	<ol> <li>Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).</li> </ol>
	<ol> <li>Sysmex America Inc., Lincolnshire, IL. XN CAL, XN CAL PF Hematology Calibrators: Calibrators for Sysmex Hematology XN-Series Analyzers, package insert.</li> </ol>
	<ol> <li>Sysmex America Inc., Lincolnshire, IL. XN CHECK Hematology Control for Sysmex XN-Series Analyzers package insert.</li> </ol>
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	<ol> <li>Koepke, John. Practical Laboratory Hematology. Churchill Livingstone Inc. 1991. p. 24-25, 36-39.</li> </ol>
	<ol> <li>Cornbleet J., Spurious results from automated hematology cell counters. Lab Medicine. 1983;8:509-514.</li> </ol>
	<ol> <li>Sysmex Reagents of America, Inc. MSDS sheets and reagent product inserts.</li> </ol>
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# **Document History Page**

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