I. POLICY STATEMENT:

Standard Operating Procedure for Sysmex XN-2000 Automated Hematology Analyzer

II. PURPOSE:

To provide operating procedures for using the XN-2000 analyzer.

III. SCOPE:

All Hematology technologists will follow this policy when performing patient testing.

IV. PRINCIPLE:

The analytical module (XN-10) is a quantitative automated hematology analyzer for *in vitro* 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 the cell interior such as the 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.

V. CLINICAL SIGNIFICANCE:

Analysis of these numerical and/or morphological findings is useful in the diagnosis of such disease states as anemia, leukemia, allergic reactions, viral, bacterial and parasitic infections.

VI. SPECIMEN:

A. Required specimen
   1. Whole blood collected in K2 EDTA preferred.
   2. Sodium Citrate may be used when EDTA platelet clumping or platelet satellitism is noted on the EDTA specimen. Use Sodium Citrate results for the platelet count and WBC count. Multiply instrument PLT AND WBC result by 1.1 to correct for anticoagulant dilution.
   3. Serous and synovial fluids should be collected in EDTA-2K anticoagulant.
   4. The use of anticoagulant with CSF specimens is neither required nor recommended.

B. Specimen volumes required
   1. Optimal draw is a 12 x 75 tube filled to capacity. The collection tube should be filled to a minimum on one mL for acceptable results. An EDTA micro-container filled above the 250ul line is adequate for testing in the open mode. Specimen should be well mixed after venipuncture.
   2. Manual analysis whole blood mode
      a. Closed tube – 1 mL
      b. Open tube – 300 µL
      c. Open microtube – 160 µL
      d. Raised Bottom microtube – 160 µL
   3. Manual analysis body fluid mode
      a. Closed tube – 1 mL
      b. Open tube – 300 µL
      c. Open microtube – 160 µL
   4. Microtainer mode – 300 µL minimum volume, 60 µL is aspirated.
   5. Unacceptable specimens including those listed below must be redrawn:
      a. Clotted samples or those containing clots, fibrin strands, or platelet clumps. All specimens will be checked visually for obvious clots prior to sampling by the analyzer.
      b. Grossly hemolyzed samples.
      c. Samples drawn above an IV line.
   6. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins.
   7. Stored Specimen Stability
      a. Stored at 4-8°C, EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability. Stored for 7 days and then disposed of.

b. 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.
c. Allow refrigerated samples to come to room temperature and mix well before analysis.

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

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

VII. SUPPLIES & REAGENTS:

1. Supplies
   a. Lint-free plastic lined lab wipes
   b. Test tubes
   c. CELLCLEAN® AUTO
   d. Sysmex reagents
   e. Commercial controls; XN CHECK™, XN CHECK™ BF

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.
   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.

a. XN REAGENTS	OPEN EXPIRATION
CELLPACK DCL	60 Days
CELLPACK DST	60 Days
CELLPACK DFL	60 Days
SULFOLYSER	60 Days (1.5L)
	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

A description of each of the Sysmex Reagents is available in the "XN-2000 Instructions for Use" manual (chapter 5) and in the instruction manual next to the XN -2000.

C. XN Reagent Replacement
1. When the reagent runs out during analysis, the analysis is paused and an error message appears in the analyzer area of the Control menu.
2. Display the [Reagent Replacement] dialog box to replace the reagent.
   a. Select the help button on the control menu
   b. Select [Execute]
      i. Remaining Reagent Volume indicator appears
3. Replacing a new diluent / hemolytic agent
   a. Display the [Reagent Replacement] dialog box
   b. Remove the cap from the new reagent container
      i. Confirm the reagent has not expired
4. Input the reagent code (barcode)
   a. Place the cursor in the reagent code field
   b. Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code
   c. Select [OK]
   d. Remove the cap from the old reagent container.
   e. Pull out the dispensing set straight up.
   f. Insert the dispensing set straight into the new container.
   g. Close the cap.
   h. Select [Execute]
      i. Reagent replacement starts. When complete, the dialog box closes automatically.
5. Replacing Dye
   a. Display the [Reagent Replacement] dialog box.
   a. Prepare the new reagent cartridge.
      i. Confirm the reagent has not expired.
   b. Open the top front cover.
   c. Pull up the cover from the reagent that is to be replaced.
      i. When the dye solution cover is pulled up, a Help dialog box appears in the IPU screen.
   d. Remove the old reagent cartridge from its holder
   e. Install the new reagent cartridge into the holder
      i. 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.
      ii. If the wrong reagent is installed, the analyzer beeps repeatedly and the Help dialog box appears in the IPU screen.
   f. Pull down the cover on the reagent until you hear a click.
      i. When the cover is pulled down, the Help dialog box closes automatically.
      ii. The ID of the new reagent is read automatically and the information is registered.

g. Close the top front cover.
   i. Reagent replacement starts.
   ii. When complete, the reagent replacement window closes automatically

* After replacing reagents, run one level of XN CHECK to validate the reagents. Edit the reagent log with a comment stating that QC has been performed.

IV. CALIBRATION AND PRECISION:

Initial calibration is performed during installation by the Sysmex Field Service Representative. Perform calibration as needed, e.g., when QC data is fluctuating. However, if the abnormality in the QC analysis data was caused by an error in the analyzer, degradation of the reagent, or degeneration of the control blood, do not perform calibration. Calibrators traceable to reference methods are used in the calibration of the analyzer.

The laboratory shall verify calibration on a continual basis to ensure accuracy of system. Calibration verification is also required if one or more of the following occur:

A. Critical parts are replaced.
B. Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.
C. When advised by Sysmex Field Service Representative.

An on-going verification of calibration is done by hematology technical staff by review and documentation of commercial control and X-BarM QC data, proficiency testing results and patient control testing results. The operator may calibrate the following parameters using XN CAL and XN CAL PF calibrator: WBC, RBC, HGB, HCT, PLT, PLT-F and RET. If a potential problem is noted, re-calibration will be performed by following the procedure located in the Sysmex "XN-2000 Instructions for Use" manual (chapter 12).

IX. QUALITY CONTROL

A. Quality control is performed in order to monitor an analyzer's performance over time. XN CHECK and XN CHECK BF is the material used to monitor the performance of the XN analyzer. It should be noted that for troubleshooting purposes, additional control runs may be necessary.
B. XN CHECK Commercial Controls Instructions for Use
   1. Remove vials from refrigerator and allow them to come to room temperature (18-25^{o}C), for approximately 15 minutes.
   2. Mix vials by gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended.
C. XN CHECK BF Commercial Body Fluid Controls Instructions for Use

1. Remove vials from refrigerator and allow them to come to room temperature (18 – 25°C) for approximately 15 minutes.
2. Mix vials by gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended.

WARNING: POTENTIALLY INFECTIOUS MATERIAL.

The human blood used in XN 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 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.

D. Frequency of Control use and review
   1. XN CHECK control levels 1, 2, and 3 will be run daily by 1st shift in the Sampler mode after the routine cleaning procedure and as needed by technical staff to check patient or instrument problems and to validate reagents after they have been changed.
   2. XN CHECK BF control levels 1 and 2 will be run by technical staff in the Manual BF mode as needed before patient samples are processed.
   3. The lead technologist will review commercial and X-BarM charts weekly.

E. XN CHECK QC Analysis
   1. Place the vial containing control blood in the rack.
   2. Place rack on sampler unit; sampler unit will auto-start.
   3. Results will be plotted on the L-J Chart as well as the Radar Chart for review.

F. XN CHECK BF Analysis
   1. Check the Status indicator LED on the analyzer to confirm analyzer is in ready state.
   2. If the tube holder is not ejected, press the mode switch. Tube holder will slide out.
   3. Select the Change Analysis Mode button on the control menu.
   4. Select [Body Fluid] mode. Analyzer will automatically perform Autorinse.
   5. Select [OK]
   6. Place thoroughly mixed vial in tube holder, press start switch.
   7. If vial barcode is unreadable, select the analyzer menu button on the control menu.
      a. Select [QC Analysis]
      b. From the list of QC files, select the file to be analyzed. Judgment dialog box will open automatically.
      c. Place thoroughly mixed vial in tube holder, press start switch.
      d. When analysis is complete, analysis results are displayed. User should review results and either accept or cancel the run. Accepting the run

will transfer the results to the L-J Chart and the Radar Chart for review.

G. Reviewing Quality Control Results
   1. QC File screen
      a. Allows for review of the latest QC results in Radar Chart format for the QC file that is selected in the list.
      b. Any point exceeding the upper or lower limit is marked with a red "X".
   2. QC Chart screen
      a. Allows for review of detailed graph data of all QC runs for selected file.
      b. Analysis data is plotted cumulatively and displayed in the chart area as a line graph.
      c. Any point exceeding the upper or lower limit is marked with a red "X".
      d. User must scroll up and down through the chart to view all parameters for each run. QC charts may be overlaid on top of each other for comparison.
         i. Select [Compare QC Files] to view QC charts registered to a single analyzer. This will compare the new lot with the current lot.
         ii. Select [Compare Analyzers] to compare QC files for the same material registered to different analyzers.

H. Quality Control Management
   1. From the QC Chart view, select the [Manage] button on the toolbar.
   2. Specify whether a QC run should be excluded from quality control
   3. Select [Not Manage] to exclude data from the following:
      a. Statistical computations (SD, Mean, CV)
      b. Variable target computation
      c. Number of data points = n
   4. An open circle will be displayed on the L-J Chart when the QC run is not managed or excluded and is not connected by a line to the adjacent QC runs.
   5. A comment will need to be added to the QC data selected by the cursor.
      a. Select [Input Any Comment] to input a free text comment.
      b. Select [Fixed Comments] to use a comment from a list of preset comments in the QC settings menu.
      c. Select [OK]
      d. A comment bubble will be displayed when a comment exists for a QC run.
      e. The comment will be visible in the comment display area when the cursor is placed on the QC run.

I. Verify that all parameters fall within the assigned assay range. If controls fall outside the range call the Sysmex Technical Assistance Center at 1-888-879-7639 to investigate possible control material failure and to obtain troubleshooting recommendations.
   1. Corrective Action for out of range QC Results
      a. Rerun the same vial of control; possible "random error".
      b. If still out, use a new vial of the same lot number of control.
      c. If control is still flagged, run the other two levels of controls.

d. If 2 out of 3 levels of controls are in; system is in control. Assess all previous results for validity.
e. Document any trouble shooting actions taken on log sheet.
f. Control results must meet acceptable criteria prior to reporting patient results.

J. New Lot QC Parallel Testing

a. At least one week before the the old lot expires, enter the New QC lot numbers and expiration dates. Refer to the "XN 2000 Instructions for Use" manual, section 8.3 for detailed instructions.
b. Parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated, Auto-set the targets.

Note: Evidence based limits for quality control are supplied by Sysmex. The mean will change for each lot of QC, while the limits remain the same.

X. OPERATING PROCEDURE:

A. Start-Up Procedure

1. Checks prior to turning on
   a. Visual inspections of analyzer / system / reagents
   b. Place completed samples into final storage area for the lab
   c. Remove any items that may interfere with operations
   d. Gather and re-locate all empty racks to designated processing or sample loading area
   e. Verify network / host connections are properly working
2. Turning ON the entire system
   a. Verify that all power switches for each device are in the ON position
   b. Press the green start-up switch on the sampler unit (left) to power ON the entire system
3. Log on to the XN-IPU
   a. When the logon dialog box appears, enter Logon name: "xn ".
4. Analyzers 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 10^3/ µL
WBC-D	0.10 x 10^3/ µL
RBC	0.02 x 106/µL
HGB	0.1 g/dL
PLT-I	10 x 10^3/ µL
PLT-F	3 x 10^3/ µL

Analyze Quality Control Material

a. Daily Cleaning

CELLCLEAN AUTO is used to clean the system. Refer to the XN-2000 *Instructions for Use* for detailed, illustrated procedures.

i. Make sure the XN analyzer is in the "Ready" state.
ii. Click the analyzer menu button.
iii. Select "Maintenance".
iv. Select "Cleaning".

A message will appear on screen and the tube holder will slide out.

v. Place a new vial of CELLCLEAN AUTO in the sample tube holder
vi. Press the blue start switch.

NOTE: Cleaning will take approximately 20 minutes. The cleaning process will conclude with a BACKGROUND CHECK and the analyzer will return to the "READY" state in the manual mode.

6. Remove the empty tube of CELLCLEAN AUTO and discard.
7. Return to step 1. and perform "Cleaning" on the other XN analyzer.

* Analyze Quality Control Material.

b.Shutdown – performed weekly

CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-2000 *Instructions for Use* for detailed, illustrated procedures.

vii. Confirm analyzers and sampler unit and are at ready.
viii. Confirm tube holders are retracted into the analyzers.
ix. Obtain empty racks

Place 2 tubes of CELLCLEAN AUTO in rack two, positions 9 and 10. This rack will shut down the XN's.

x. Place racks on sampler unit, sampler unit will auto-start.

After shutdown is complete, the XN-IPU will shutdown, the XN analyzers will power off . Remove the racks.

Wait 30 seconds before performing the start up procedure.

xi. XN on-board maintenance history will auto-populate.

* Analyze Quality Control Material.

c. Patient Processing

d. System Analysis (sampler analysis) - XN

a. Make sure the analyzer and the sampler are in READY state
b. Check that tube holder has retracted into the analyzer, press mode button if necessary.
c. Place sample(s) in rack(s) in right sampler pool (analyzer side)
d. Rack(s) will auto-start.
e. Samples will run, results will be displayed in the IPU.
f. On-Board rules engine will determine repeat or reflex testing
g. Rack will run in reverse to perform repeat or reflex testing.
h. Remove the rack from the left sampler pool when analysis in completed
i. Make smear if indicated.

Manual Analysis – XN

WARNING: Potential biohazard exposure when handling open patient specimens. Follow Standard precautions outlined by laboratory safety guidelines.
Recommended: Wear gloves, a lab coat and safety glasses. Use plastic lined gauze when opening.

j. Check the status of the analyzer. Confirm the analyzer is ready.
k. Press the mode switch to eject the tube holder.
l. Select the Change Analysis Mode button on the control menu
m. 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.
n. Select [OK]
o. Select Manual Analysis button on the control menu
p. Input sample ID or select [Read ID]
q. If running a raised bottom microtube, select RBT and place in the front tube holder.
r. Select [OK]
s. Properly mix the specimen and place in the tube holder
    If running microtainer, remove the cap using caution to avoid splattering.
t. Press the start switch on the analyzer
    The tube holder will slide in and the sample will be aspirated
    When the analysis is complete, the tube holder slides out
u. Remove the sample, repeat steps for additional samples
v. Review results in IPU to determine whether repeat or reflex testing is required. Rerun sample if required. Make smear if required.

e. Body Fluid Analysis – XN

a. Check the status of the analyzer. Confirm the analyzer is ready.
b. Press the mode switch to eject the tube holder.
c. Select the Change Analysis Mode button on the control menu.
d. Select [Body Fluid]
e. Select [OK]
    The analyzer will automatically perform a background check up to three times.
f. Select the Manual Analysis button on the control menu
g. Input the sample ID or select [Read ID]
h. Select [OK]
i. Properly mix the specimen and place in tube holder.
    If running microtainer, remove the cap using caution to avoid splattering
j. Press the start switch on the analyzer
    The tube holder will slide in and the sample will be aspirated
    When the analysis is complete, the tube holder slides out
k. Remove the sample
l. Perform Background check prior to running additional samples if indicated
m. Return analyzer to Whole Blood mode prior to running whole blood samples.

XI. REPORTING RESULTS:

A. Adult Reference Ranges (18 years and greater)

Parameter	Reference Range	Parameter	Reference Range
WBC:	3.59 – 10.24 x 10^3 uL	Neut %	41.40 – 77.94 %
RBC	Female 3.83 – 5.15 10^6 ul	Lymph %	11.20 – 44.30 %
	Male 4.00 – 5.66 10^6 ul	Mono %	4.02 -13.69 %
HGB	Female 11.50 – 15.30 g/dL	Eo %	0.00 – 5.81 %
	Male 11.86 – 17.06 g/dL	Baso %	0.06 – 1.33 %
HCT	Female 35.23 – 46.93 %	IG %	0.00 – 1.27 %
	Male 36.54 – 51.41 %	Neut #	1.42 – 6.94 x 10^3 ul
MCV	80.00 – 100.00 fL	Lymph #	0.62 – 3.14 x 10^3 ul
MCH:	27.03 – 32.78 pg	Mono #	0.22 – 0.98 x 10^3 ul
MCHC:	30.76 – 34.74 g/dL	Eo #	0.00 – 0.40 x 10^3 ul
RDW	36.23 – 49.77 fL	Baso #	0.00 – 0.09 x 10^3 ul
PLT:	119.34 – 363.26 x 10^3 ul	MPV	8.99 –12.89 fL
RET #	0.01 –0.13 10^6 ul	RET %	0.66–2.39$10^6$ ul
IRF %	0.42–15.98 %	RET HE	30.94–39.21 pg
IG #	0.00–0.10 x 10^3 ul	IPF	0.00–8.12 %
		IPF #	0.00–17.99 x 10^3 ul

B. Pediatric Reference Ranges-
Please see Pediatric Policy found in the Hematology Manual

C. Critical Results

TEST	LOW	HIGH
Absolute Neutrophil Count	<0.50 th/mm^3	
CSF Count		≥10 or more WBC/mm^3
Hematocrit – Whole Blood	<21%	
Hemoglobin -Whole Blood	< 7.0 g/dL	
Peripheral Smear		≥ 5% blasts
Platelet Count	< 20.0 th/mm^3	
White Blood Cells	< 2.0 th/mm^3	31 days – adult >30.0 th/mm^3 7 days – 30 days >40.0 th/mm^3 0 – 7 days >45 th/mm^3
Hemoglobin	< 7.0 g/dL	

XII. LIMITATIONS OF PROCEDURE:

A. XN-Series Manufacturer Stated Linearity for Whole Blood

Parameter	Range	Units
WBC	0-440.0	$x10^3/\mu L$
RBC	0-8.60	$x10^6/\mu L$
HGB	0-26.0	g/dL
HCT	0-75.0	%
PLT, PLT-F	0-5000	$x10^3/\mu L$
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. When using a diluting fluid you must run a background count on that fluid prior to running the diluted specimen. This will ensure that there is nothing that will interfere with the count.
2.Note the use of dilution for linearity on the patient report.

B. XN-Series Manufacturer Stated Linearity for Body Fluids

Parameter	Range	Units
WBC-BF	0.003-10.000	$x10^3/\mu L$
RBC-BF	0.003-5.000	$x10^6/\mu L$
TC-BF	0.001-12.412	

1. Sample results with Error related to WBC-BF, RBC_BF and TC-BF# parameters should not be used.

2. TC-BF counts <0.001 x 10^3/uL should be reported as <1.

3. RBC-BF counts <0.003 X 10^6/uL should be reported as <3000

4. Bronchial Lavage and clear colorless spinal fluid specimens cannot be run on the XN-2000.

C. 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. Incubate suspected cold agglutinins at 37 degrees and rerun in manual mode.
5.Extremely elevated WBCs may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values. Make a 1:7 dilution to obtain a more accurate HGB.

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.

8. 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. Recollect the specimen in Sodium Citrate anticoagulant and multiply by 1.1 dilution factor.

9.Abnormal paraproteins found in Multiple Myeloma patients can falsely increase the HGB. To correct HGB perform plasma replacement. Try a 1:7 dilution for the WBC and PLT.

10. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:7 dilution with CELLPACK.

10. Rocking specimen excessively, may affect the WBC differential.

11. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers. If the WBC estimate indicates a false elevation, count the Megakaryocytes and correct like nucleated reds.

REFERENCES:

1.Sysmex XN-2000 *Instructions for Use* (North American Edition), Sysmex Corporation, Kobe, Japan.

2.Sysmex XN series *Administrator's Guide* (North American Edition), Sysmex Corporation, Kobe, Japan

3.Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).

4.Sysmex America Inc., Lincolnshire, IL. XN CAL, XN CAL PF Hematology Calibrators: Calibrators for Sysmex Hematology XN-Series Analyzers, package insert.

5.Sysmex America Inc., Lincolnshire, IL. XN CHECK Hematology Control for Sysmex XN-Series Analyzers package insert.

6.Sysmex America Inc., Mundelein, IL. Sysmex ***Insight*** Participant Overview Guide.

7.Koepke, John. *Practical Laboratory Hematology.* Churchill Livingstone Inc. 1991.

p. 24-25, 36-39.

8.Cornbleet J., *Spurious results from automated hematology cell counters. Lab Medicine.* 1983;8:509-514.

9.Sysmex Reagents of America, Inc. MSDS sheets and reagent product inserts.

10. College of American Pathologists (CAP) Hematology-Coagulation Checklist, July 2012.

11. Stewart, Charles and Koepke, John. *Basic Quality Assurance Practices for Clinical Laboratories*, Van Nostrand Reinhold, 1989, p 189.

12. Gulati GL, Asselta A, Chen C. *Using vortex to disaggregate platelet clumps*, Laboratory Medicine, 28:665, 1997.

13. Zhou X, Xiaoli W. *Amikacin Can Be Added to Blood to Reduce the Fall in Platelet Count*, American Journal of Clinical Pathology, 136:646-652, 2011.

14. MCV Reference range - *Wintrobe MM* Clinical Hematology 8th ed. Philadelphia: *Lea and Fibiger; 1984*.

Henry JB Clinical Diagnosis and Management by Laboratory Methods. 17 ed. *Philadelphia WB Saunders Co; 1984*

Miale JB. Laboratory Medicine: Hematology. 6th ed. *St Louis MO: CV Mosby; 1982*

Williams WJ, Beutler E, Erslev AJ, Lichman MA. Hematology. 3rd ed. *New York, NY: McGraw-Hill Book Co.;1983.*

XIV. MAINTENANCE AND STORAGE:

a. All policies and procedures are reviewed every two years by Laboratory Administration and or the Medical Director of the Laboratory or designee.
b. The Laboratory Administration and Medical Director review policies and procedures when there are changes in practice standards, or requirements.
c. All policies and procedures are reviewed every two years by staff or at the time new or revised ones are put in effect.
d. All policies are retained 8 years after being discontinued or revised.
e. All procedures are retained 2 years after being discontinued or revised.

UPP Laboratory is a CAP accredited facility, as of 7/1/11 the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

POLICY CREATION : Sheanea LaCock	***Date 5/23/18***
Author: ***Sheanea LaCock***	
Medical Director:	

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
SECTION MEDICAL DIRECTOR		

REVISION HISTORY (began tracking 2011)

Rev	Description of Change			Author		Effective Date
Lead	**Date**	**Coordinator/ Manager**	**Date**	**Medical Director**		**Date**
Sheanea LaCock	5/23/18					