1. **PRINCIPLE**

The XN-2000 consists of two hematology analytical modules. 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.

**II SPECIMEN REQUIREMENTS**

 **Peripheral Blood**

* + 1. Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant
* NOTE: Smear preparation on specimens older than 4 hours may exhibit a loss of cellular integrity. Please follow laboratory protocol for smear preparation and review

 **C. Specimen volumes required**

* + 1. Optimal draw is a 12 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 – XN-3100 & XN-2000
			1. Closed tube – 1 mL minimum sample volume, 88 μL is aspirated
			2. Open tube – 300 μL minimum sample volume, 88 μL is aspirated
			3. Open micro tube – 160 μL minimum sample volume, 88 μL is aspirated
			4. RBT (Raised B - 250µ minimum sample volume, 88µ is aspirated
	1. **Unacceptable specimens**

The following specimens listed below should be rejected:

* + 1. 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.
		2. Grossly hemolyzed samples
		3. Samples drawn above an IV line
	1. **Characteristics that may affect test results**:
1. Lipemia
2. Icterus
3. cold agglutinins.
	1. **Stored Specimen Stability**
		1. Stored at 4-8oC, 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.
	2. **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.

1. **SUPPLIES & REAGENTS**
	1. **Supplies**
		1. De-ionized water
		2. Lint-free plastic lined lab wipes
		3. Gauze
		4. Test tubes
		5. Plastic squeeze bottles
		6. CELLCLEAN® AUTO
		7. Sysmex reagents
		8. Commercial controls; XN CHECKTM, XN CHECKTM BF
		9. Microscope slides, frosted with rounded / clipped corners
			1. 76 x 26 mm; 0.9 – 1.2 mm thick
	2. **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.

XN REAGENTS OPEN EXPIRATION

CELLPACK DCL 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

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

CELLPACK DCL Stability

1. Unopened, it is 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 MSDS 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 does not have ingredients with those characteristics.

 2. CELLPACK DFL (DFL): Whole blood diluents for use in hematology analyzers; used

 in combination with Fluorocell™ RET for the analysis of reticulocytes, or with Fluorocell

 PLT for the analysis of platelets 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, it is stable until expiration date printed on the container.
2. Opened, stable for 60 Days.

CELLPACK DST Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS 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.

limit/threshold limit values or have been identified as carcinogens. CELLSHEATH(C) does not have ingredients with those characteristics.

1. **Lysing Reagents**
	* 1. 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.

SULFOLYSER Storage

1. Store at 1o-30oC away from direct sunlight.
2. Allow the container to equilibrate to environmental temperature (15-30o) prior to use.
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.

SULFOLYSER Stability

1. Unopened, it is 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 MSDS 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 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, and nucleated red blood cell percentage are analyzed.

Lysercell WNR Storage

1. Store at 2o-35oC away from direct sunlight.
2. Allow the container to equilibrate to environmental temperature (15-30o) prior to use.
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 WNR Stability

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

Lysercell WNR Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS 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 WNR 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, immature granulocytes, lymphocytes, monocytes, and eosinophils are analyzed.

Lysercell WDF Storage

1. Store at 2o-35oC away from direct sunlight.
2. Allow the container to equilibrate to environmental temperature (15-30o) prior to use.
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, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Lysercell WDF Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS 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 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.

Fluorocell WNR Storage

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

Fluorocell WNR Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Fluorocell WNR Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS 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 MSDS; Fluorocell WNR is harmful if swallowed.

* + 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, it is 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 MSDS 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 MSDS.

* + 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, it is 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 MSDS 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 MSDS

* + 1. Fluorocell PLT: Used to stain the platelets in diluted blood samples for the assay of platelet counts in blood.

Fluorocell PLT Storage

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

Fluorocell PLT Stability

1. Unopened, it is stable until expiration date printed on the container.
2. Opened, stable for 90 Days.

Fluorocell PLT Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS 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 MSDS.

* 1. **Cleaning Agent**
		1. 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-50.

CELLCLEAN AUTO Storage

1. Store at 1-25oC, away from direct sunlight.
2. Do not use the reagent if it is suspected to have frozen.

CELLCLEAN AUTO Stability

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

CELLCLEAN AUTO Hazard Risk

**WARNING:**

* The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS 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 MSDS; CELLCLEAN AUTO is corrosive and may cause burns to skin.
	1. **Deionized water**

pH ~7.0 (Millipore)]

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

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

XN CAL Storage

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

XN CAL Stability

* + - 1. Unopened and properly stored, XN CAL is stable until the expiration date printed on the unopened vial.
			2. Open vial stability is 4 hours.

 **2. XN CALTM PF**: for use in calibrating the analyzer for PLT-F (platelet count obtained from

the PLT-F channel)

XN CAL PF Storage

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

XN CAL PF Stability

a. Unopened and properly stored, XN CAL PF is stable until the expiration date printed on the unopened vial.

b. Open vial stability is 4 hours.

**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.

* 1. **XN Reagent Replacement**
		1. When the reagent runs out during XN 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.
			1. Select the help button on the control menu
			2. Select [Execute]
				1. Remaining Reagent Volume indicator appears
		3. Replacing a new diluent / hemolytic agent
			1. Display the [Reagent Replacement] dialog box
			2. Remove the cap from the new reagent container
				1. Confirm the reagent has not expired
			3. Input the reagent code (barcode)
				1. Place the cursor in the reagent code field
				2. Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code
				3. Select [OK]
			4. Remove the cap from the old reagent container.
			5. Pull out the dispensing set straight up.
			6. Insert the dispensing set straight into the new container.
			7. Close the cap.
			8. Select [Execute]
				1. Reagent replacement starts. When complete, the dialog box closes automatically.
1. Replacing Stain
	* + 1. Display the [Reagent Replacement] dialog box.
			2. Prepare the new reagent cartridge.
				1. Confirm the reagent has not expired.
			3. Open the top front cover.
			4. Pull up the cover from the reagent that is to be replaced.
				1. When the stain solution cover is pulled up, a Help dialog box appears in the IPU screen.
			5. Remove the old reagent cartridge from its holder
			6. 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 stain 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.
			7. Pull down the cover on the reagent until you hear a click.
				1. When the cover is pulled down, the Help dialog box closes automatically.
				2. The ID of the new reagent is read automatically and the information is registered.
			8. Close the top front cover.
				1. Reagent replacement starts.
				2. When complete, the reagent replacement window closes automatically.
2. **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.

Calibration is verified every six months or on an "as-needed" basis to ensure accuracy of system. Calibration verification is also required if one or more of the following occur:

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

Calibration verification may be performed by review and documentation of commercial control and, 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.

**Before calibration, ensure that the XN is both clean and precise.**

1. **Precision Check**
2. Perform routine maintenance on the analyzer and perform a background count to ensure counts are within acceptable limits.
3. Verify that there is sufficient volume of all reagents. Precision and Calibration procedures will be aborted if the XN runs out of reagent.
4. Obtain a sample of fresh normal whole blood. **Do not** use commercial controls or calibrators for precision. The blood donor specimen should:
5. Be from a healthy person who is not taking any medication
6. Have morphologically and numerically normal CBC.
7. Be drawn in a potassium EDTA anticoagulant tube using proper collection technique.
8. Have a minimum of 2.5 mL of sample.
9. On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready
10. If the tube holder has not ejected out, press the mode switch
11. Select the Change Analysis Mode button on the control menu and select Whole Blood
12. Select [OK] to close the dialog box
13. Select the Analyzer menu button on the control menu
14. Select [Calibration] – [Precision Check]
15. Mix the vial containing the sample – 10 end-over-end inversions confirming cell button is dispersed
16. Place the vial in the sample tube holder
17. Press the start switch on the analyzer
18. The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer
19. The tube holder will slide out when analysis is complete
20. The results are displayed in the [Precision Check] analysis dialog box.

a. If the analysis results do not satisfy conditions for normal results, or if results are outside acceptable limits, the test numbers of the tests that must be repeated are displayed. Select and redo the manual analysis.

1. When all analysis results satisfy the conditions, select [OK] in the dialog box.
2. Select [Yes] to record passing precision results in the precision check history.

NOTE: If an error occurs during analysis and the analysis can no longer continue, stop precision check. Once the error is cleared, redo the manual analysis.

1. **Calibration – XN CAL**
2. On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready
3. If the tube holder has not ejected out, press the mode switch
4. Select the Change Analysis Mode button on the control menu and select Whole Blood
5. Select [OK] to close the dialog box
6. Select the Analyzer menu button on the control menu
7. Select [Calibration] – [Calibrator Calibration]
8. Mix the vial containing the calibrator according to package insert
9. Place the vial in the sample tube holder
10. Press the start switch on the analyzer
11. The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer
12. The tube holder will slide out when analysis is complete
13. The results are displayed in the [Calibrator Calibration] analysis dialog box.
14. If the analysis results do not satisfy conditions for normal results, or if results are outside acceptable limits, the test numbers of the tests that must be repeated are displayed. Select and redo the manual analysis.
15. When all analysis results satisfy the conditions, select [Calibration] in the dialog box.
16. Select [OK] to display results in the [Calibrator Calibration] execution dialog box.
17. Select the check box to include the calibration parameter in the calibration exercise, clear the check box to exclude the parameter in the calibration exercise. If a parameter meets all of the following criteria, the check box will automatically be selected:
	* + 1. 80% < New Rate < 120%
			2. New Rate – Current Rate < +5
			3. Range Value < Max Range
			4. Acceptable Limit < Delta Percent < Service Limit

If a parameter meets all of the conditions and the Delta Percent is less than the Acceptable Limit, it is excluded from calibration as there is no need for calibration.

If a parameter does not meet all of the conditions and the Delta Percent is greater than the Acceptable Limit, the calibration cannot be performed. Calibration is performed with the parameter excluded.

Selecting the check box enables you to manually enter a value in [New Rate (%)]. A range of 80% to 120% may be entered.

1. Select [OK] to update the compensation rates. The calibration process is logged in

 the calibrator calibration history.

1. **Calibration – XN CAL PF**
2. On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready
3. If the tube holder has not ejected out, press the mode switch
4. Select the Change Analysis Mode button on the control menu and select Whole Blood
5. Select [OK] to close the dialog box
6. Select the Analyzer menu button on the control menu
7. Select [Calibration] – [Calibrator Calibration (PLT-F)]
8. Mix the vial containing the calibrator according to package insert
9. Place the vial in the sample tube holder
10. Press the start switch on the analyzer
11. The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer
12. The tube holder will slide out when analysis is complete
13. The results are displayed in the [Calibrator Calibration (PLT-F)] analysis dialog box.
14. If the analysis results do not satisfy conditions for normal results, or if results are outside acceptable limits, the test numbers of the tests that must be repeated are displayed. Select and redo the manual analysis.
15. When all analysis results satisfy the conditions, select [Calibration] in the dialog box.
16. Select [OK] to display results in the [Calibrator Calibration (PLT-F)] execution dialog box.
17. Select the check box to include the calibration parameter in the calibration (PLT-F) exercise, clear the check box to exclude the parameter in the calibration exercise. If the parameter meets all of the following criteria, the check box will automatically be selected:
	* + 1. 80% < New Rate < 120%
			2. New Rate – Current Rate < +5
			3. Range Value < Max Range
			4. Acceptable Limit < Delta Percent < Service Limit

If the parameter meets all of the conditions and the Delta Percent is less than the Acceptable Limit, it is excluded from calibration as there is no need for calibration.

If the parameter does not meet all of the conditions and the Delta Percent is greater than the Acceptable Limit, the calibration cannot be performed. Selecting the check box enables you to manually enter a value in [New Rate (%)]. A range of 80% to 120% may be entered.

1. Select [OK] to update the compensation rate. The calibration process is logged in the calibrator calibration history.

**NOTE**: If an error occurs during analysis and the analysis can no longer continue, stop precision check. Once the error is cleared, redo the manual analysis.

1. **QUALITY CONTROL**

Quality control is performed in order to monitor an analyzer’s performance over time. XN CHECKand XN CHECK BF is the material used to monitor the performance of the XN analyzer.

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

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

 XN CHECK control levels 1,2 and 3 will be run every 12 hours as assigned per facility.

**NOTE: You can periodically display a message to prompt the user to perform quality control tasks through the QC Settings Menu.**

1. **Registering and modifying a QC file – lot information input**
	1. Select [QC File] Icon
	2. Select TAB for analyzer from bottom of QC File screen
	3. Select File number to be registered.
	4. Select [Register] button on toolbar
	5. Enter lot information
		1. Material
		2. Lot Number
		3. Expiration Date
	6. Highlight all parameters and select [Restore]
		1. Browse XN QC Limits folder on XN-IPU Desktop
		2. Select file for QC to be registered
		3. Select Open.
		4. Sysmex Range Limit %’s will automatically upload to the file
	7. Repeat for each level of XN CHECK, XN CHECK BF to be registered and for each module in the XN configuration
	8. To modify an existing QC File, select the QC File and [Modify] from the toolbar. Update the Lot No, Exp. Date as appropriate.
	9. Perform parallel studies between production lot and new lot prior to production lot expiration.
2. **XN CHECK QC Analysis**
3. Place the vial containing control blood in the rack.
4. Place rack on sampler unit; sampler unit will auto-start.
5. Results will be plotted on the L-J Chart as well as the Radar Chart for review.
6. **Auto Set Targets**
7. Parallel test new controls by analyzing the chosen levels of control, a minimum of twice a day for 5 days prior to expiration or previous lot. After a minimum of 10 data points are accumulated, auto set the targets.
	* 1. Select QC Chart
		2. Select [Range] and set cursors so that every data point is included
		3. Select [Register]
		4. Highlight all parameters and select [Auto Setting]
		5. Confirm that the check box for TARGET ONLY is set. Do not select the check box for LIMIT.
		6. Select [OK]; the target for each parameter will be calculated and set for the duration of the QC lot.
		7. Repeat steps for each new lot of QC being moved into production.
		8. Confirm the target set falls within the range of means provided on the XN Check assay sheet provided.
8. **Reviewing Quality Control Results**
9. **QC File screen**
10. Allows for review of the latest QC results in Radar Chart format for the QC file that is selected in the list.
11. Any point exceeding the upper or lower limit is marked with a red “X”.
12. **QC Chart screen**
13. Allows for review of detailed graph data of all QC runs for selected file.
14. Analysis data is plotted cumulatively and displayed in the chart area as a line graph.
15. Any point exceeding the upper or lower limit is marked with a red “X”.
16. User must scroll up and down through the chart to view all parameters for each run.
17. Select [Range] to set a main cursor and a sub-cursor so that data between the two cursors can be manipulated.
	* + 1. Statistics may be analyzed over any selected range.
			2. Targets may be auto-set for the selected range.
			3. To cancel range mode, select [Range] on the toolbar again or exit QC Chart mode.
18. QC charts may be overlaid on top of each other for comparison.

(1) Select [Compare QC Files] to view QC charts registered to a single analyzer. This will compare the new lot with the current lot.

(2) Select [Compare Analyzers] to compare QC files for the same material registered to different analyzers.

1. **Tolerance**

2 out of 3 control results must be within tolerance before reporting patient results for each respective test. Out of control situations must be resolved and any action taken to resolve these situations must be documented in the appropriate action log.

1. **Quality Control Management**
2. From the QC Chart view, select the [Manage] button on the toolbar.
3. Specify whether a QC run should be excluded from quality control
4. Select [Not Manage] to exclude data from the following:
5. Statistical computations (SD, Mean, CV)
6. Variable target computation
7. Number of data points = n
8. 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.
9. A comment may be added to the QC data selected by the cursor
10. Select [Input Any Comment] to input a free text comment.
11. Select [Fixed Comments] to use a comment from a list of preset comments in the QC settings menu.
12. Select [OK]
13. A comment bubble will be displayed when a comment exists for a QC run.
14. The comment will be visible in the comment display area when the cursor is placed on the QC run.
15. **Recording and Storage of QC Data**
16. Printing and saving QC Data
17. Select QC Files Icon and highlight file to output.
18. Select QC Chart Icon
19. Set Range of points to output by clicking [Range] and capturing the points with the cursors
20. Select [output] to print the selected chart to either GP or LP
21. Select [file] to save the data to removable media
22. ***Insight*TM** Quality Assurance Program (QAP)

The laboratory maintains an SNCS connection, the QC results will transmit automatically to ***Insigh***t after each run. There is no need to batch upload the data to ***Insight***.

**For the Alice location**:

The ***Insight*** account number is 30828

The XN Left (A) SN # is 36598 The XN Right (B) SN # 37660

**For the Beeville location**:

The ***Insight*** account number is 30868

The XN Left (A) SN # is 38404 The XN Right (B) SN # 38409

**For the Kleberg location**:

The ***Insight*** account number is 30919

The XN Left (A) SN # is 36598 The XN Right (B) SN # 37660

The lead technologist or a 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 lot has 2 data submission dates, approximately every 30 days for the 84-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 IPU’s hard drive.
	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: 1-888-879-7639 (1-888-8SYSMEX).
1. **Operating Procedure**
	1. **Start-Up Procedure**
		1. Checks prior to turning on
			1. Place completed samples into final storage area for the lab
			2. Remove any items that may interfere with operations
			3. Gather and re-locate all empty racks to designated processing or sample loading

 area, verify network / host connections are properly working

* + - 1. Verify sufficient reagent supply is nearby
			2. Ensure that all power switches are on the “on” positions (if applicable)
		1. Press and release the green master switch on theXN-2000 sampler unit
			1. The status indicator LED will flash green
			2. The XN-IPU will automatically turn on
			3. Each XN analyzer will begin start-up

 3. The XN screen will display the log on

1. Type “ADMIN” for the username
2. Type “m116m” for the password

 4. .Analyzer self-checks

 **XN**

1. Initialization of the mechanical parts;
2. Rinsing of the hydraulic units
3. Temperature stabilization
4. 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 103/ μL |
| PLT-F | 3 x 103/ μL |

5. Analyze Quality Control Material

* 1. **Patient Sample Processing**
1. System Analysis (sampler analysis**)**
	* + 1. Make sure the analyzer and the sampler are in READY state
			2. Check that tube holder has retracted into the analyzer, press mode button if necessary
			3. Place sample(s) in rack(s) in right sampler pool (analyzer side)
			4. Rack(s) will auto-start.
			5. Samples will run, results will be displayed in the IPU.
			6. On-Board or WAM rules engine will determine repeat or reflex testing
			7. Rack will run in reverse to perform repeat or reflex testing.
			8. Remove the rack from the left sampler pool when analysis in completed.
		1. Manual Analysis - XN
			1. Check the status of the analyzer. Confirm the analyzer is ready.
			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. Select Manual Analysis button on the control menu
			7. Input sample ID or select [Read ID]
			8. Properly mix the specimen and place in the front tube holder
				+ If running microtainer, remove the cap using caution to avoid splattering, select ***CAP OFF***, and place in the rear tube holder
				+ If running an RBT [Raised bottom tube] select the [Raised Bottom Tube] radio button and place specimen in the front tube holder with ***CAP ON***
2. Select OK
3. 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
1. Remove the sample, repeat steps for additional samples
2. Review results in IPU to determine whether repeat or reflex testing was performed or smear review is required.
	* 1. Off-line analysis
			1. Press mode switch on the sampler
			2. Verify sampler is in READY state
			3. Place the rack in the right pool of the sampler for the analyzer that you wish to use.
			4. Transport begins automatically
			5. Remove the rack from the left sampler pool after analysis is complete
			6. Press the mode switch on the sampler to place the system back into system

 Mode

1. **MAINTENANCE – (See Procedure H-03)**
2. **PROCEDURAL NOTES AND CALCULATIONS**
	1. If making a dilution of a patient specimen and running in XN Whole Blood mode, multiply the parameters by the dilution factor
	2. 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
	3. Use the Help function on the SP-50 when errors and messages display. Use the error icon on the XN to display help menu.
	4. While slides are being processed on the SP smear table, the START key may not be available for manual mode processing
	5. During normal processing of slides on the SP-50, Maintenance., Settings, and Shutdown functions are not available.
	6. Current settings for XN and SP-50 should be recorded and maintained in the XN-Series Resource Manual and the SP-Series Implementation Manual.
	7. Current on-board rules should be exported and saved on external storage device. A printout of the rules should be inserted in the XN-Series Resource Manual.
	8. **Do not** place samples on a mechanical rocker. Excessive mixing may alter white cell membranes resulting in false interpretive messages.
	9. For troubleshooting specifics refer to the Sysmex XN-3100 & XN-2000 *Instructions for Use*
3. **REPORTING RESULTS**

Reference Ranges are reported with every result. See H-13 for reference values.

1. **REPORTING ABNORMAL RESULTS TO PHYSICIANS**:

**Criteria for performing a Manual Differential**

|  |  |
| --- | --- |
| WBC | <2.0 mm³  |
| Neutrophil Absolute # | >20.0 |
| Lymphocyte Absolute # | >5.0 |
| Monocyte Absolute # | >1.5 (1000) |
| Eosinophils Absolute # | >1.5 (1000) |
| Basophils Absolute # | >1.0 (1000) |
| Immature Granulocytes % | >5.0 % |
| Neutrophil % | <30% or >85% |
| Lymphocyte | >Neut or <5% |
| Monocytes | >15% |
| Basophils | >2.5% |

 **Criteria for review of RBC Morphology:**

First specimen received by laboratory on an admission will have a RBC morphology performed if the following criteria are met:

* + - Hct: <25%
		- MCV <75 or >105
		- RDW >22
		- Hypo, Aniso, Micro, Macro analyzer flags.

All subsequent specimens will have the comment that the RBC Morphology has been previously reviewed.

1. **LIMITATIONS OF PROCEDURE**
2. XN-Series Manufacturer Stated Linearity:

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Range** | **Units** |
| WBC | 0-440.0  | x103/μL |
| RBC | 0-8.60  | x106/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.
3. Possible Sample Interferences
4. Specimens must be free of clots and fibrin strands.
5. 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.
6. 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.
7. 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.
8. Extremely elevated WBCs may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values.
9. Severely hemolyzed samples (*in vitro*) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
10. 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.
11. Abnormal paraproteins found in Multiple Myeloma patients can falsely increase the HGB. To correct HGB perform plasma replacement.
12. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK.
13. Rocking specimen excessively, may affect the WBC differential.
14. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.
15. Flagging and Action Messages

Abnormal samples on the SN-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 (e.g., Difference between WNR and WDF. Check the results) \_The results are displayed in the Browser Screen

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

1. **REFERENCES**
2. Sysmex XN-3100 & XN-2000 *Instructions for Use* (North American Edition), Sysmex Corporation, Kobe, Japan.
3. Sysmex XN series *Administrator’s Guide* (North American Edition), Sysmex Corporation, Kobe, Japan
4. Sysmex SP-50 *Instructions for Use [3 volumes]* (North American Edition), Sysmex Corporation, Kobe, Japan.
* Basic Operation
* General Instructions
* Troubleshooting
1. Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).
2. Sysmex America Inc., Lincolnshire, IL. XN CAL, XN CAL PF Hematology Calibrators: Calibrators for Sysmex Hematology XN-Series Analyzers, package insert.
3. Sysmex America Inc., Lincolnshire, IL. XN CHECK Hematology Control for Sysmex XN-Series Analyzers package insert.
4. Sysmex America Inc., Mundelein, IL. Sysmex ***Insight***Participant Overview Guide.
5. Koepke, John. *Practical Laboratory Hematology.* Churchill Livingstone Inc. 1991.

p. 24-25, 36-39.

1. Cornbleet J., *Spurious results from automated hematology cell counters. Lab Medicine.* 1983;8:509-514.
2. Sysmex Reagents of America, Inc. MSDS sheets and reagent product inserts.
3. College of American Pathologists (CAP) Hematology-Coagulation Checklist, July 2012.
4. Stewart, Charles and Koepke, John.  *Basic Quality Assurance Practices for Clinical Laboratories*, Van Nostrand Reinhold, 1989, p 189.
5. Gulati GL, Asselta A, Chen C. *Using vortex to disaggregate platelet clumps*, Laboratory Medicine, 28:665, 1997.
6. 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.
7. Sysmex XN-Series Automated Hematology Systems Flagging Interpretation Guide, Document Number: 1166-LSS, Rev 3, January 2017

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