 4840-HE-0601

**Sysmex XN-9100 Automated Hematology Analyzer**

1. **PRINCIPLE**

The Sysmex XN-9100 is an integrated system that incorporates two hematology analytical analyzers as well as an automated slidemaker/stainer.

The XN-10 analytical modules are quantitative automated hematology analyzers for *in vitro* diagnostic use in determining 32 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.

Directly Measured Parameters: WBC, RBC, HGB, HCT, RDW-SD, PLT-I, PLT-F, NEUT%, LYMPH%, MONO%, EO%, BASO%, IG%, NRBC#, WBC-BF, RBC-BF, TC-BF, BF-PMN%, BF-MN%, RETIC%, RET-H*e*, IRF%, IPF%

Calculated Parameters: MCV, MCH, MCHC, RDW-CV, MPV, NEUT#, LYMPH#, MONO#, EO#, BASO#, IG#, NRBC%, RETIC#, IPF#, BF-PMN#, BF-MN#.

The Sysmex SP-50TM 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 applying hematocrit information from the host computer (if available) to determine optimum smearing criteria. Prepared and labeled smears are shuttled to stain area where they will then be transferred through the various sections to be stained, rinsed, and then dried. The intervals within each section of the staining process are laboratory defined. Completed smears from staining process are placed into slide magazines ready for review.

The SP-50 analyzer also provides a manual mode smear and stain operation where sample volumes and/or tubes that do not meet requirements for rack operations can be placed in the manual position of the instrument to be aspirated for smear and stain process. In addition, the system also allows for pre-made smears to be routed to the staining process. The unit is self-monitoring and alarms sound when operation is interrupted.

Slides prepared by the Sysmex SP-50 are used for differentiation and morphologic evaluation of cellular elements of whole blood.

**II. SPECIMEN REQUIREMENTS**

* 1. **Peripheral Blood**
		1. Whole blood should be collected in a Potassium EDTA-2K or EDTA-3K tube with a minimum of 1.0ml of blood or a potassium EDTA Microtainer filled above the 250 µL line.
		2. Manual analysis whole blood mode
			1. Closed tube – 1 mL, 88 µL is aspirated.
			2. Open tube – 300 µL, 88 µL is aspirated.
			3. Raised bottom tube – 250 µL, 88 µL is aspirated.

 **B. Body Fluid for Analysis on the XN-9100**

. 1. Approved Body Fluid sample types for the **XN-9100** are:

* Peritoneal
* Pleural
* Synovial Fluid
* CSF

 2. These fluid types should be collected in EDTA-2K anticoagulant.

 3. CSF – no anticoagulant required or recommended.

 **C.** Manual analysis body fluid mode – **XN-9100**

* + - 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.
		1. Manual analysis – **SP-50**
			1. Closed tube smear and staining – 500 μL minimum sample volume, 70 μL is aspirated.
			2. Open tube smear and staining - 300 μL minimum sample volume, 70 μL is aspirated.
			3. Raised bottom tube - 250 μL minimum sample volume, 70 μL is aspirated.
	1. **Unacceptable specimens**

Unacceptable specimens should be rejected and may include:

* Those containing fibrin or clots
* Excessive platelet clumping
* Substandard mixing or collection
* Expired or improperly stored collection tubes
* Improperly filled tubes based on collection tube manufacturer’s guidelines
* Specimens contaminated with IV fluid
	1. **Characteristics that may affect test results**:
1. Lipemia
2. Icterus
3. Cold agglutinins.
4. Hemolysis
	1. **Stored Specimen Stability**
		1. Stored at 2-8oC, 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**

**A. Sysmex Reagents**

 1. All reagents are used at room temperature and are to be used within the manufacturer’s

 expiration date on each container.

 2. Record date received on container.

 3. 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™ 60 Days (1.5L)

 Lysercell™ WNR 60 Days

Fluorocell™ WNR 90 Days

Lysercell WDF 90 Days

Fluorocell WDF 90 Days

Fluorocell RET 90 Days

Fluorocell PLT 90 Days

**SP REAGENTS**

 ColorWright Wright Stain

6.8 Concentrated Phosphate Buffer

Methanol, anhydrous (99.9%)

Nerl High Purity Water

CELLPACK DCL 60 Days

**D. 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-50.

1. If frozen, thaw and mix thoroughly before using.
2. CELLPACK DCL is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace

2. CELLPACK DST (DST): Concentrated diluent of reagent for use in hematology analyzers.

1. If frozen, thaw and mix thoroughly before using.
2. CELLPACK DST is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.

3. 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.

1. Do not use the reagent if it is suspected to have frozen.
2. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.
	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.

1. Allow the container to equilibrate to environmental temperature (15-30oC) prior to use.
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.
	* 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.
4. Allow the container to equilibrate to environmental temperature (15-30oC) prior to use.
5. Do not use the reagent if it is suspected to have been frozen.
6. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.
	* 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.
7. Allow the container to equilibrate to environmental temperature (15-30oC) prior to use.
8. Do not use the reagent if it is suspected to have been frozen.
9. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.
	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.
10. Do not use the reagent if it is suspected to have frozen.
11. Hazard Risk: Acute tox: Harmful if swallowed
	* 1. Fluorocell WDF: Used to stain the leukocytes in diluted and lysed blood samples for determination of differential count in blood.
12. Do not use the reagent if it is suspected to have been frozen.
13. Hazard Risk:

 1. Health hazard: May cause damage to organs

 2. Acute tox: Harmful if swallowed

* + 1. Fluorocell RET: Used to stain the reticulocytes in diluted blood samples
1. Do not use the reagent if it is suspected to have been frozen.
2. Hazard Risk:

 1. Flammable liquid and vapor

 2. Health hazard: may cause damage to organs

 3. Acute tox: Harmful if swallowed

* + 1. Fluorocell PLT: Used to stain the platelets in diluted blood samples
1. Do not use the reagent if it is suspected to have been frozen.
2. PLT Hazard Risk: Acute tox: Harmful if swallowed.

* 1. **Cleaning Agent**
		1. CELLCLEAN AUTO: 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.
1. Store away from direct sunlight.
2. Do not use the reagent if it is suspected to have frozen.
3. Cellclean Auto Hazard Risk: Cellclean Auto is corrosive and may cause burns to skin.
	1. **Stain / Buffer for SP-50**
		1. Romanowsky stain (Wright)
			1. Used to fix and stain blood cells for the purpose of differentiation and morphologic evaluation.
			2. Do not use reagent if it is suspected to have frozen.
			3. Acute tox: Stain contains methanol. Methanol is flammable and poisonous. Potential human carcinogen. May be fatal if ingested and harmful if inhaled. Causes irritation to eyes, skin and respiratory tract.
		2. Phosphate Buffer pH 6.8 (Concentrated)
			1. Used for the preparation of blood smears by the Automated hematology slide .

Preparation Unit SP-50.

* + - 1. Do not use if reagent is expired or has been frozen.
			2. NEVER allow contact with skin and eyes and avoid ingesting. In case of contact with

 eyes, rinse immediately with water or normal saline. If swallowed seek medical advice

 immediately.

* 1. **Methyl Alcohol (Methanol), anhydrous (99.9%) for SP-50**
		1. Used for cleaning of the stain system and staining pools. Also may be used for optional cleaning of the spreader glass.

**WARNING:** Methanol is flammable and poisonous. Potential human carcinogen. May be fatal if ingested. Harmful if inhaled. Causes irritation to eyes, skin and respiratory tract.

* 1. **Nerl high Purity water** pH ~7.0
		+ 1. Replace reagent if it is showing signs of contamination or instability such as

cloudiness of discoloration.

* 1. **Commercial Control Material for XN analyzers**
		1. **XN CHECKTM, L1, L2 and L3**
1. Storage
	* Store vials at 2-8oC.Do not freeze or expose to excessive heat.
2. 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 opened and expiration 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 package insert assay expected ranges after appropriate troubleshooting.
	* If deterioration is suspected, call the Sysmex Technical Assistance Center.
	* 1-888-879-7639 (1-888-8SYSMEX).

* + 1. **XN CHECKTM BF, L1 and L2**
1. Storage
	* Store vials at 2-8oC.
	* Do not freeze or expose to excessive heat.
2. Stability
	* Unopened and properly stored, XN CHECK BF is stable until the expiration date printed on the unopened vial.
	* Open vial stability is 30 days when promptly refrigerated after each use.
	* Record the opened and expiration date on each vial upon opening or cap piercing.
	* Heat or freezing can damage XN CHECK BF without gross visible changes. Deterioration is suspected when the mean of the control results is not within the package insert 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.** Use universal blood and body fluid precautions

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

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

 b. Stability: Unopened and properly stored, XN CAL is stable until the expiration date printed on

 the unopened vial.

 c. 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 - 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.** Use universal blood and body fluid precautions

* 1. **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].
				+ 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.
				+ Confirm the reagent has not expired.
			3. Input the reagent code (barcode).
				+ Place the cursor in the reagent code field.
				+ Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.
				+ 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].
				+ Reagent replacement starts. When complete, the dialog box closes automatically.
		4. **Replacing Dye**

 Display the [Reagent Replacement] dialog box.

* + - 1. Prepare the new reagent cartridge.
				1. Confirm the reagent has not expired.
			2. Open the top front cover.
			3. 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.
			4. Remove the old reagent cartridge from its holder.
			5. 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.
			6. 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.
			7. Close the top front cover.
				1. Reagent replacement starts.
				2. When complete, the reagent replacement window closes automatically.

**6. SP-50 Reagent Replacement**

The following is a list of replacement messages and the reagent requiring replacement:

|  |  |
| --- | --- |
| **MESSAGE** | **REAGENT** |
| Out of CELLPACK DCL | CELLPACK DCL |
| Out of Stain Solution 1 | Stain 1 |
| Out of rinse water | Deionized Water |
| Out of methanol | Methanol |
| Out of phosphate buffer | Buffer |

1. When a reagent container is empty, an error occurs and an alarm sounds.
2. Touch [Execute] in the [HELP] dialog box. The [Reagent Replenishment] dialog box appears.
3. Touch the Reagent that needs replacement.
4. Load the new reagent using a clean technique. Avoid placing spout kits or sensors on a contaminated surface.

 e. Input the new reagent information.

1. CELLPACK DCL
* Select [Replace the Reagent] checkbox.
* Touch inside the Reagent Code box and scan the Reagent Code on the box of CELLPACK DCL.
* Touch [Execute].
1. Stains, Buffers, Methanol and Water
* Follow steps above.
* Touch [Execute].

 ***CAUTION:***

* Do not use the reagent outside of the written intended use, or not according to the written directions for use.
* When replacing this reagent, do not refill and use the same container.
* Handle the reagent with care to prevent air bubbles from foaming.
* Do not use expired reagents.
* If the reagent is removed after it has been connected, (i.e. opened), it may become contaminated with bacteria causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
* NEVER allow contact of the reagent with the human body. Avoid contact with skin and eyes, and avoid ingestion. If it comes in contact with the skin, rinse skin thoroughly. If it gets in the eye, rinse with large amounts of water and seek immediate medical attention. If swallowed, seek medical advice immediately.
* Before use, please read the safety data sheet carefully.

 **IV. PRECISION and CALIBRATION**

Initial analyzer precision and calibration is performed during installation by the Sysmex

 Service Engineer (SE).  Calibrators traceable to reference methods are used in the

 calibration of the analyzer.  Documentation of parameters that can be calibrated and reference methods for calibrator assay value assignments are contained in the calibrator package inserts.

The calibration of Sysmex hematology analyzers does not expire and is not reagent lot dependent. Per the XN-Series IFU, calibration should be performed only when indicated. Calibration of an analyzer should only be completed when:

* Installation activity occurs
* Critical parts or assemblies are replaced. ***(See “Managed*** ***Calibration Addendum” for a reference of critical parts for your analyzer)***
* Calibration Verification fails (QC values are outside of acceptable limits) and troubleshooting indicates that there is no major underlying problem with the analyzer, reagents or quality control materials.
* When advised by a Sysmex Representative.

 Calibration verification may be performed by:

* Following manufacturer’s instruction for instrument operation
* Testing at least two levels of control materials each day, whereby the controls meet the laboratory’s criteria of acceptability.
* Review and documentation of commercial QC and X-BarM QC data
* Proficiency testing results
* Patient control testing results.

 Calibration verification may also be accomplished by processing a

 commercial calibrator and comparing results to those published on the calibrator assay

 sheet.

***Prior to performing calibration, Maintenance and Precision must be performed to 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 EDTA-2K or EDTA-3K anticoagulant tube using the collection guidelines specified by the tube manufacturer.
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 CALTM**
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.
2. **Calibration – XN CALTM PF**
3. On the main unit, check the Status indicator LED. Confirm the LED is **green** indicating the analyzer is Ready.
4. If the tube holder has not ejected out, press the mode switch.
5. Select the Change Analysis Mode button on the control menu and select Whole Blood.
6. Select [OK] to close the dialog box.
7. Select the Analyzer menu button on the control menu.
8. Select [Calibration] – [Calibrator Calibration (PLT-F)].
9. Mix the vial containing the calibrator according to package insert.
10. Place the vial in the sample tube holder.
11. Press the start switch on the analyzer.
12. The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer.
13. The tube holder will slide out when analysis is complete.

 c. Mix the tube by inversion prior to initiating the next aspiration.

1. The results are displayed in the [Calibrator Calibration (PLT-F)] analysis dialog box.
2. 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.
3. When all analysis results satisfy the conditions, select [Calibration] in the dialog box.
4. Select [OK] to display results in the [Calibrator Calibration (PLT-F)] execution dialog box.
5. 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.

**V. QUALITY CONTROL**

Quality control is performed in order to monitor an analyzer’s performance over time. XN CHECKTM and XN CHECKTM BF is the material used to monitor the performance of the XN-Series analyzer. A minimum of 2 levels of controls are needed to be run at least once every 24 hours. It should be noted that for troubleshooting purposes, additional control runs may be necessary. All troubleshooting actions are logged in the Activity Log.

To QC the **SP-50**, examine a stained smear from the routine workload for smear and stain quality on a daily basis. Document results on appropriate log.

1. **XN CHECKTM** Commercial Controls Instructions for Use
2. Remove vials from refrigerator and allow them to come to room temperature (18-25oC), for approximately 15 minutes.
3. Mix vials according to the package insert accompanying the product until the cell button in the bottom of the vial is completely suspended.
4. **XN CHECKTM BF** Commercial Body Fluid Controls Instructions for Use

1. Remove vials from refrigerator and allow them to come to room temperature (18 –

 25oC) for approximately 15 minutes.

2. Mix vials according to the package insert accompanying the product until the cell

 button in the bottom of the vial is completely suspended.

**WARNING: POTENTIALLY INFECTIOUS MATERIAL.**

 Use universal blood and body fluid precautions

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

***Three levels of XN Check and two levels of XN Check BF will be run every 24 hours on days of patient testing.***

SP-50 QC slide will be evaluated daily.

**D. Registering and modifying a QC file**

**Registering a QC file *Without* BCQMh Program**

* 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. Select desired XN CHECK Level or XN CHECK BF Level from drop down box:

a. Material

b. Enter Lot Number

c. Expiration Date

* 1. Select [Restore]

a. Browse XN QC Limits folder on XN-IPU Desktop.

b. Select file for QC to be registered.

c. Select [Open].

 d. Sysmex Range Limit %’s will automatically upload to the file.

* 1. Repeat for each level of XN CHECK, XN CHECK BF to be registered and for each module in the XN configuration.
	2. To modify an existing QC File, select the QC File and [Modify] from the toolbar. Update the Lot No, Exp. Date as appropriate.
	3. Perform parallel studies between production lot and new lot prior to production lot expiration.

**E. XN CHECK QC Analysis**

1. Place the vial containing control blood in the designated QC (**red**) rack labelled SRQA A1.
2. Place rack on the feeder. The rack will automatically advance and send QC material to each module.
3. Results will automatically be sent to the ***Insight*** and the BCQM*h* programs, be plotted on the L-J Chart and 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 an Autorinse and background count.
5. Select [OK].
6. Select Manual Analysis button on the control menu.
7. Select Read ID [the QC Barcode will be scanned by the analyzer]

(Make sure [CAP OPEN] is NOT selected).

1. Place thoroughly mixed vial in tube holder, press start switch.
2. If vial barcode is unreadable, select the analyzer menu button on the control menu.
	* 1. Select [QC Analysis]
		2. From the list of QC files, select the file to be analyzed and click OK. Judgment dialog box will open automatically.
		3. Place thoroughly mixed vial in tube holder, press start switch.
		4. 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 ***Insight*** and BCQM*h* programs, be plotted on the L-J Chart and the Radar Chart for review.

**H. Reviewing Quality Control Results**

**Reviewing and Managing With BCQM Program**

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

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

 analysis.

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

 steps for returning to analysis ready.

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

 recommended corrective action.

* **Resolve -** is activated if a QC error has been detected. Follow prompts to the

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

 perform the troubleshooting action.

* **QC is overdue -** end user needs to analyze QC since it exceeds the timeframe

 determined by the preferences screen.

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

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

***Follow the BCQMh for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability.***

***QC data is acceptable if:***

1. All controls are within +/- 2SD of mean.
2. Two controls are within +/- 2SD and the other is between 2-3 SD of the mean.

 **QC data is not acceptable if:**

1. One control is greater than 3 SD of the mean.
2. Two or three controls are greater than +/- 2SD
3. One control is between 2-3 SD of the mean on two successive runs.

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

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

**K. SP-50 Daily QC Slide Review**

1. Review the blood smears macroscopically for acceptability:
2. Smears are sufficient length (greater than half the length of the unfrosted portion of the slide).
3. The feathered edge becomes gradually thinner without streaks, holes, or tails.
4. Even, consistent staining of blood smear.
5. Review the blood smears microscopically for acceptability:
6. Relatively even distribution of cellular elements.
7. Acceptable morphology within the working area.
8. None or very little artifact of the cell morphology, (e. g., “punched-out” RBC’s, smashed WBC’s).
9. None, or very little stain precipitate or debris.
10. The staining is consistent and imparts the characteristic cytoplasmic color differences and distinct nuclear chromatic patterns of the whole spectrum of blood cells. Acceptable stains will display the following characteristics:
* RBC’s should be pink to orange. There should be good differentiation between normochromic, hypochromic, and polychromatic cells.
* Lymphocytes will display dark purple nuclei with varying shades of blue cytoplasm.
* Neutrophils will display dark purple nuclei, with light pink cytoplasm and lilac granules.
* Monocytes will show lighter purple nuclei. The cytoplasm of the monocytes will be gray-blue with reddish granules.
* Eosinophils show bright orange granules in the cytoplasm.
* Basophils display dark blue granules in the cytoplasm.
* Platelets will be violet to purple.

|  |  |
| --- | --- |
| **PROBLEM** | **RESOLUTION** |
| * WBC’S too light in color
* RBC’s and/or PLT’s too light in color
* RBC’s are too red in color or too blue
 | * Verify that stain times have not changed. (Refer to “current laboratory settings” in the document for current settings).
* Replace external stain container. Perform “Replace Stain” (Refer to “Maintenance” in this document).
* Perform “Shutdown 2” procedure (Refer to “Maintenance” in this document).
* Check pH of buffer. Replace buffer is pH has changed.
* Check pH of deionized water. Replace, if necessary.
* Make and stain a test smear.
 |
| * Stain Precipitate
 | * Replace external stain container. Perform “Replace stain”. (Refer to “Maintenance” in this document)
* Check sip tube on stain container and make sure it is 1 inch from the bottom of the container.
* Clean the staining part (Refer to “Maintenance” and “Rinse Devices” in this document.
* Perform Shutdown 2; clean the stain baths of excess precipitate. (Refer to “Maintenance” and Clean the stain baths” in this document.
* Make and stain a test smear.
 |
| * Water Artifact
 | * Perform Stain Replenishment.
* Clean the staining part (refer to “Maintenance” and “Rinse Devices” in this document.
* Make and stain a test smear.

If water artifact is still observed:1. Replace external stain container. Perform “Stain Replacement” (Refer to “Maintenance” in this document).
2. Add methanol prefix to stain conditions.

Make and stain a test smear. |

**If the above troubleshooting steps do not resolve the problem, notify your supervisor and/or key operator when available, or call the Sysmex Technical Assistance Center (TAC) at 1-888-879-7639.**

***Document all problems/Corrective action(s) in the analyzer’s action log.***

**VI. Operating Procedure**

 **A. Start-Up Procedure**

* + 1. Checks prior to power on:
			1. Ensure that the SP-50 towers (slide supply cassettes) have sufficient slides. Fill

with glass slides. See procedure for loading glass slides in “as needed maintenance” in this document.

* + - 1. Verify sufficient reagent supply is nearby.
			2. Ensure empty grey magazines are loaded onto the SP-50 feed out block.
			3. Ensure that all power switches are on the “on” positions.
			4. The status indicator LED will flash **green**.
			5. The XN-IPU will automatically turn on.
			6. The SP-50 will begin start-up.
			7. The SP-50 Dialog box will appear.
* Touch the name of the user to be logged on.
* Enter the Password and touch [OK].

**NOTE:** If auto logon is enabled, the [SP-50 IPU Logon] dialog box does not appear.

 Display of the user name varies depending on the number of users.

h. Each XN analyzer will begin start-up. The XN screen will display the login. Enter

 user name and password.

4. Analyzer self-checks

 **XN**

1. 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 |
| WBC-P *(XN-20 only)* | 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 |
| WBC-BF | 0.001 x 103/ μL |
| RBC-BF | 0.003 x 106/μL |

5. Analyze Quality Control Material on all systems.

**B. Patient Sample Processing**

1. **System Analysis (sample analysis)**
	* + 1. Make sure the analyzers and the conveyors 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) on the feeder.
			4. CBC tubes have LIS barcoded labels that download patient demographics to the XN and print out on reports.
			5. Place top of the label directly below the cap and make sure the label is straight with the barcode running vertically on the tube with the name at the top of the tube.
			6. Rack(s) will automatically be pushed forward and routed to the analyzers.
			7. Samples will run, results will be displayed in the IPU.
			8. On-Board or Sysmex Caresphere rules engine will determine repeat or reflex testing.
			9. Rack will run in reverse to perform repeat or reflex testing.
			10. If smear is required, rack will be transported to SP-50 via conveyor unit and samples will be aspirated by SP-50.
			11. SP-50 prepares and stains peripheral blood smears and transports the prepared smears in grey magazines to the magazine storage location as the final destination.
			12. If no smears are required, rack will be transported to the collector unit without stopping at the SP-50.
			13. Remove the rack from the collector unit when analysis in completed.
			14. If processing Raised Bottom Tubes in the sampler analysis mode, the special

 RBT rack (rack with yellow stripe, special barcode and special plug in position

 one) **MUST** be used. **Do not place** Raised Bottom Tubes into a regular XN

 sample rack.

* + 1. **Manual Analysis - XN**
			1. Confirm the analyzer and the sampler are in READY 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.
				- [Body Fluid] Select to perform body fluid analysis. *(Follow BF procedure below)*
			5. Select [OK].
			6. Select Manual Analysis button on the control menu.
			7. Input sample ID or select [Read ID].
				- 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.***
1. Select [OK].

j. **Properly mix the specimen** and place in the front tube holder.

 k. 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.

 l. Remove the sample, repeat steps for additional samples.

 m. Review results in IPU to determine whether repeat or reflex testing was performed

 or smear review is required.

* + 1. **Body Fluid Analysis - XN**
			1. Confirm the analyzer is in Ready 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]
			5. Select [OK].
				- The analyzer will automatically perform a background check up to three times if the first two fail.
			6. Select the [Manual Analysis] button on the control menu.
			7. Input the sample ID or select [Read ID].
			8. Select [OK].

**NOTE:** BF mode will automatically select state of [Cap Open]. Remove check if using

 regular sample tubes.

* + - 1. **Properly mix the specimen** and place in tube holder.
			2. 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.
			3. Remove the sample.

 l. Background check is required prior to running additional samples if the analyzer

 alerts you with the error message “Analysis result is high”. The following values

 trigger this message:

* WBC-BF and TC-BF# > 100.00 x 102/μL
* RBC-BF > 100.0 x 104/μL

 Sample will be displayed with Red background in Sample Explorer.

 m. Return analyzer to Whole Blood mode prior to running whole blood samples.

* + 1. **Off-line analysis**

The sampler for the analyzer, or the sampler for the SP-50 is separated from the conveyor unit of the overall system and can be operated as a standalone device.

* + - 1. Press mode switch on the control panel located on the conveyor unit.
			2. Verify conveyor is in READY state. Analysis mode indicator will turn orange.
			3. Place the rack in the designated area in the right sampler pool of the XN analyzer you wish to use.
			4. Rack transport begins automatically.
			5. Remove the rack from the left sampler pool of the analyzer after analysis is

Completed.

* + - 1. Press the mode switch on the conveyor unit to place the system back into system

 Mode.

* [Query to host to retrieve the host order from the LIS.
* [Additional rinse count] 3 additional rinses can be added.

 **NOTE:** If the icon is “greyed out”, the setting is OFF in the general settings

 menu. See SP-50 [Basic Operation] manual – Chapter 5 for

 additional information.

* + 1. **SP-50 Manual Preparation – [Staining only]**

Use this procedure when you want to:

* Stain a smear sample from peripheral blood that was prepared manually.
* Stain a smear sample from a body fluid that was prepared manually.

***NOTE: Do not stain Fecal Smears on SP –Series Analyzers!***

1. Load a properly labelled smear into a magazine.
* Slides should be loaded with the frosted part of the slide facing to the front.
1. Open the manual magazine holder cover forward and down.
2. Pull out either the left or right manual magazine holder.
3. Load the magazine that holds the glass slide in the manual magazine holder.
4. Push in the manual magazine holder.
5. Close the manual magazine holder cover.
6. Check the instrument and status display LED of the manual magazine holder. Wait until the status LED light turns green.
7. If the sample tube holder is not ejected out, press the [Mode Switch] on the main unit.
8. Touch [Select Mode] in the status area.
9. Touch [Staining].
10. Touch [OK].
11. Touch [Manual] in the status area to change the smear preparation conditions (**optional**). Then touch [OK].
12. Press the start switch to start the staining process.
13. Press the mode switch on the main unit to return the analyzer to sampler mode and to retract the tube holder.
14. If the analyzer was in “off line” analysis, press the mode select switch on the control panel of the conveyor to return the analyzer to on line analysis.
15. Slides will be placed in the magazine and fed out to the magazine storage unit.
16. Remove the prepared smears.
	* 1. **SP-50 - Printing only**

Use this procedure when you want to print the sample information such as the sample number or barcode on the glass slide.

1. Open the manual magazine holder cover.
2. Pull out the manual magazine holder.
3. Load an empty magazine into the manual magazine holder and push it inside the analyzer.
4. Close the manual magazine holder cover. Wait for the **green** LED light to illuminate.
5. If the sample tube holder is not ejected out, press the mode switch on the main unit.
6. Touch [Select Mode] in the status area.
7. Touch [Print].
8. Touch [OK].
9. Touch [Manual] in the status area to change the smear preparation condition (**optional**).
10. Touch [Sample Number] and scan the barcode number with the handheld barcode reader or type the Specimen ID# manual or select the checkbox to read the sample barcode ID# with the barcode reader of on the main unit.
11. Touch [OK].
12. Press the start switch on the main unit.
13. Press the mode switch on the analyzer to return the analyzer to sampler mode and retract the tube holder.
14. If the analyzer is in “off line” mode, press the mode select switch on the control panel of the conveyor to return the analyzer to “on line” mode.
15. Remove the prepared smears from the manual magazine holder.
16. **MAINTENANCE**
17. **Daily – XN-10 and SP-50 analyzers**
18. **Shutdown**

Shutdown can be performed either in the System Mode or Manual Mode. Shutdown can also be performed on the entire system or on individual analyzers if the laboratory desires to have one analyzer available at all times.

**NOTE:** Performing the rinse procedure in the sampler mode using the **Blue** rack is

 considered a “cleaning” procedure and will never power down the

 instruments. In order to perform daily and weekly maintenance on the

 SP-50 stain baths – you must perform the shutdown procedure in manual

 mode via the SP-50 menu.

|  |  |  |
| --- | --- | --- |
| Rack | Color Stripe | Usage |
| SRRA A1 | Blue- Cleaning Process | Performs Cleaning Process only of entire line. Do not use on SP-50. Power off of analyzers must be performed manually.  |
| SRSA A1 | Green – Shutdown | Performs Cleaning and Shutdown of entire line including SP-50  |
| SRQA A1 | Red - QC | Sends QC to entire line |
|   |

1. **Shutdown entire system (powers off analyzers) – System Mode**
2. Confirm analyzers, conveyor unit and SP-50 are at ready and not in “off line” mode.
3. Confirm glass slides are loaded and an empty magazine is loaded in the manual magazine holder.
4. Confirm tube holders are retracted into the analyzers.
5. Obtain empty **green** maintenance rack labeled SRSA A1.
	* Place one tube of CELLCLEAN AUTO in the rack for each module or SP-50 requiring maintenance beginning with position 10 and load backwards

(e.g., if there are 3 XN modules and 1 SP-50 – load 4 tubes of CELLCLEAN AUTO in positions 7-10).

 ***CAUTION:***

* Use one vial of CELLCLEAN AUTO for each instrument. Do not reuse CELLCLEAN AUTO that has previously been used.
* During Shutdown, other sample tubes are not accepted.
1. Load the racks onto the feeder, rack will automatically convey to the analyzers.
2. Shutdown is performed automatically.
3. Remove the glass slide used for cleaning in the manual magazine holder on the SP-50.
4. Remove the tubes of CELLCLEAN AUTO from the racks.
5. XN and SP-50 on-board maintenance will auto-populate.
	* When SP-50 cleaning is complete, it will automatically power off.
	* When XN cleaning is complete, each XN will Power off.
6. **Rinse entire XN Analyzers – NO SP-50– System Mode**

a. Confirm analyzers, conveyor unit and SP-50 are at ready and not in “off line”

 mode.

b. Confirm glass slides are loaded and an empty magazine is loaded in the

 manual magazine holder.

c. Confirm tube holders are retracted into the analyzers.

d. Obtain empty **blue** maintenance rack labeled SRRA A1.

* + Place one tube of CELLCLEAN AUTO in the rack for each XN module requiring maintenance beginning with position 10 and load backwards

(e.g., if there are 2 XN modules– load tubes of CELLCLEAN AUTO in positions 9-10).

e. Load the racks onto the feeder, rack will automatically convey to the

 analyzers.

f. When XN cleaning is complete, each XN will go through startup, ending with a

 background check.

g. Manually begin Shutdown1 or Shutdown2 on the SP-50 analyzer.

1. **Shutdown individual analyzers – “off line” mode**

This procedure allows the operator the option of cleaning both analyzers on the conveyor or only one analyzer.

1. Confirm the analyzer to be shutdown is in the Ready mode.
2. Confirm tube holders are retracted into the analyzers.
3. Confirm glass sides are loaded and there is sufficient reagent on the SP-50.
4. Confirm conveyor(s) are in “off line analysis” mode for the analyzers that you wish to shutdown.
5. Obtain the **blue** rack with SRRA A1 label.
6. Place CELLCLEAN AUTO in position 10 if cleaning only one analyzer, or in positions 9 and 10 if cleaning both analyzers.
7. Load the rack onto the right sampler pool (analyzer side).
8. Shutdown is performed automatically on the analyzer dedicated to the tube position.
* When SP-50 cleaning is complete, it will automatically power off, and then immediately power on and begin startup.
* When XN cleaning is complete, each XN will go through startup, ending with a background check.
1. Remove the tube(s) of CELLCLEAN AUTO from the rack(s) and discard.
2. XN and SP on board maintenance will auto populate.
3. **Daily Cleaning – Manual Mode - XN Analyzers only**

 Daily “Cleaning” can be used as an alternative to the daily “Shutdown” procedure

 to keep one analyzer up and running at all times and to allow for rack flow to the

 alternate analyzer.

1. Make sure the analyzer is in the “Ready” state.
2. Click the analyzer menu button.
3. Select **[Maintenance].**
4. Select **[Cleaning].**
5. The tube holder will slide out.
6. Place a vial of CELLCLEAN AUTO in the sample tube holder.
7. Press the blue start switch.
8. Remove the tube of CELLCLEAN AUTO from the rack and discard.

 **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.

1. **Shutting down the conveyors.**

 If the shutdown procedures for the XN’s have already been completed, turn OFF

 the conveyor units.

a. Hold down the green master start-up switch on the conveyor either in

 Front of the BT unit or in front of the Tube sorter for approximately 3 seconds

 until the status LED light turns off.

b. The conveyors will now be turned off.

c. Follow the instructions for System Start Up in Section VI.

 **6) Shutdown – SP-50 – Manual Mode**

1. Confirm glass slides are loaded and there is sufficient reagent.
2. Confirm an empty magazine is loaded in the manual magazine holder.
3. Touch **[Menu]** on the tool bar.
4. Touch **[Shutdown].** A dialog box appears and the sample tube holder slides forward.
* Select [Shutdown1] or [Shutdown2].
1. Set CELLCLEAN AUTO in the sample tube holder.

 **CAUTION:**

* Do NOT reuse CELLCLEAN AUTO that has been previously used.
* During Shutdown, other sample tubes are not accepted.
1. Press the start switch on the main unit. The sample tube holder is retracted into the instrument.
2. Shutdown is automatically performed. Once the CELLCLEAN AUTO is aspirated, the sample tube holder will be ejected.

**REMOVE THE CELLCLEAN AUTO FROM THE TUBE HOLDER AND DISCARD.**

1. Once the shutdown has completed, the analyzer will turn off.
2. Remove the glass slide used for cleaning in the manual magazine.
3. SP-50 on-board maintenance will auto-populate.
4. **Inspect the Staining Pool – SP-50** - ***Perform this DAILY for optimum performance***

The staining pools may collect a buildup of stain precipitate daily, especially if using a Giemsa based stain. After the analyzer completes the shutdown procedure, inspect the staining pool for stain precipitate and wipe clean with methanol if necessary.

 **CAUTION:** Make sure the analyzer power is off when performing this procedure.

* Wear adequate personal protective equipment.
* Methanol is flammable at room temperature. Read all warnings and any included documentation before using the reagent.
1. Open the staining part cover.
2. Open the staining pool cover forward and down, and lift and remove the 2 staining pools. Cover opening area with absorbent towels to protect from drips.
* use a lint free lab wipe or gauze to lift the stain pool from the stain area to avoid splashes or drips of residual stain from the stain baths.

 c. Place the stain pools in a container used for cleaning.

d. With a squeeze bottle filled with methanol, spray each stain pool with

 methanol and wipe dry with a lint free cloth or gauze.

e. Reinstall the staining pools taking care to replace each pool in their proper

 placements.

f. Replace the staining pool cover and close the staining part cover.

1. **Weekly Maintenance**
2. **Shutdown 2 – SP-50**

Perform [Shutdown2] once a week or more frequently if using a stain with a high precipitate level such as Giemsa based stains. Shutdown2 fills the stain chamber with methanol. Methanol drains and the chamber fills with stain the next time the power is turned on.

Follow the instructions for Daily Shutdown for SP-50 Section A – Daily Maintenance

* Replace [Shutdown2] for [Shutdown1] in the Shutdown Menu. ***OR***
* Shutdown2 is automatically performed according to the SP-50 analyzer settings or if 40 days have passed since the last Shutdown2.

 **NOTE**: Please refer to the SP-50 Basic Operation Manual – Chapter 5 – Instrument

 Settings for additional information on programming the frequency of

 Shutdown2 settings. This setting triggers Shutdown2 automatically when

 the setting date occurs and the rack is placed at the beginning of the

 system.

1. **Clean the Staining Pool**

The stain pool may collect a buildup of stain precipitate. When [Shutdown2] is completed, or when stain precipitate is clearly visible on the stain baths, clean the staining pool.

 ***CAUTION:***

* Make sure the analyzer power is ***OFF*** when performing this procedure.
* Wear adequate personal protective equipment such as protective gloves, a protective mask, protective eyewear, and a lab coat when working.
* Methanol is flammable at room temperature. Read all warnings and any included documentation before using the reagent.
1. Prepare a container with methanol to use for the cleaning process.
2. Remove all magazines from the magazine feed out block.
3. Open the staining pool cover forward and down, lift and remove the 2 staining pools. Cover opening area with absorbent towels to protect from drips.
* Use a lint free lab wipe or gauze to lift the stain pool from the stain area to avoid splashes or drips of residual stain from the stain baths.
1. Put the staining pools in the container for cleaning and lightly stir to clean.

 ***CAUTION:*** Do not allow the stain baths to soak for more than 30 minutes. Doing so

 may cause deformation or alteration of the staining pool.

1. Add methanol to the container covering both staining pools completely.
2. Dry the staining pools with a lint free cloth or gauze.
3. Re-install the 2 staining pools using care that the correct staining pool is in the proper staining bath.
4. Replace staining pool covers and close the staining part cover
5. **Clean the spreader glass**

To maintain smear quality for a longer period, the instrument cleans the spreader glass with CELLCLEAN AUTO each time shutdown is performed. However, spreader glass debris should be manually wiped off once a week. A dirty spreader glass reduces smear quality.

1. Touch [Maintenance] in the menu screen.
2. Touch [Replacement].
3. Touch [replace spread glass].
4. Make sure that the smear unit cover is closed and touch [OK].
5. Open the slide set unit cover.
6. Make sure that the status display LED on the slide set unit lights in green or red.
7. Remove the slide supply cassette from the slide set unit.
8. Close the slide set unit cover.
9. Open the smear unit cover.
10. Rotate the fan forward and down. The spreader glass is directly behind the fan.
11. Wipe off the surface of the spreader glass with gauze moistened with methanol.
12. If spreader glass is still not clean after wiping with methanol, wipe with gauze moistened with CELLCLEAN AUTO. Insert the spreader glass with gauze moistened with water as the final step to remove the CELLCLEAN AUTO.
13. Replace the fan in its original position.
14. Close the smear unit cover.
15. Open the slide set unit cover.
16. Install the slide supply cassette.
17. Close the slide set unit cover.
18. Touch [Cancel] so as to not reset the spread glass operation count.
19. Touch [OK].
20. **As Needed Maintenance – SP-50**
21. **Loading glass slides**

When slide supply cassettes are empty, an audible error sounds and a [Help] dialog box appears.

1. Open the slide set unit cover.
2. Confirm that the status display LED on the right set unit lights in green or red.
3. Remove the slide supply cassette[s] from the slide set unit.
4. Remove the slide supply cassette guide[s].
5. Load the new glass slides so that the frosted part faces upward and toward the cassette opening.
6. Install the slide supply cassette guide[s].
7. Install the slide supply cassette[s].
8. Close the slide set unit cover.
9. Touch [Confirm] in the help dialog box.
10. **Clean Slide Magazines**

Visually check slide magazines for debris. Clean with lukewarm water and detergent. Allow to dry before replacing.

1. **Change Spreader Glass**

When the error message [Replace spreader glass] appears, the spreader glass must be replaced.

1. Follow the instructions for [Cleaning the spreader glass] under weekly maintenance and stop after step (j) is completed.
2. Remove the spreader glass from the holder by grasping the spreader glass and pulling it forward.
3. Set the new spreader glass in the holder.
* Set the spreader glass so that the edge with the small beveled edge faces forward.
* Insert the spreader glass all the way into the spreader glass holder until it stops.
1. Replace the fan in its original position.
2. Close the smear unit cover.
3. Open the slide set unit cover.
4. Install the slide supply cassette.
5. Close the slide set unit cover.
6. Touch [OK] to return the smear unit to the home position.
7. Touch [OK] to reset the spread glass operation count.
8. **Replace the Ink Ribbon**

When the error message [No Ink Ribbon] appears, replace the ink ribbon. When replacing the ink ribbon, clean ribbon holder and print head.

1. Open the slide set unit cover.
2. Confirm that the status display LED on the slide set unit lights in green or red.
3. Remove the slide supply cassette from the slide set unit.
4. Close the slide set unit cover.
5. Open the smear part cover.
6. Rotate the fan forward and down.
7. Remove the ribbon cartridge.
* Touch [Confirm] in the [Help] dialog box to continue.
* Grasp the knob, slide the bracket to the left, and move the ribbon cartridge to the removal position.
* Lift the ribbon cartridge and remove the hook pin from the bracket
* Remove the ribbon cartridge.
1. Lift both rollers of the ink ribbon and remove the used ink ribbon.
* Clean the ribbon holder and print head with 70% isopropyl alcohol wipes.
1. Insert the new ink ribbon down into the ribbon cartridge.
2. Mount the ink ribbon into the ribbon cartridge.
3. Remove the slack in the ribbon.
4. Install the ribbon cartridge onto the bracket.
5. Replace the fan in its original position.
6. Close the smear part cover.
7. Open the slide set unit cover.
8. Install the slide supply cassette.
9. Close the slide set unit cover.
10. Touch [Execute].
11. **Cleaning the Smear Part and/or Stain Unit**
12. Touch [Maintenance] in the menu screen.
13. Touch [Rinse devices].
14. Touch [Cleaning]. The tube holder slides out forward.
15. Touch [Smear Part] or [Smear Part and Stain Unit].
* If the whole blood aspiration line is dirty or clogged, touch [Smear Part].
* If the whole blood aspiration line is dirty and/or the stain unit needs to be cleaned and refreshed, touch [Smear Part and Stain Unit].
1. Set CELLCLEAN AUTO in the front sample tube holder.
2. Press the start switch on the main unit. The sample holder retracts and aspiration begins.
3. When aspiration is complete, the sample tube holder slides out forward. Remove the CELLCLEAN AUTO tube and discard.
4. Press the mode switch on the main unit to return the analyzer to sampler mode and retract the sample tube holder.
5. **Replacing the fuse**

Over current protection fuses are used in the main unit and pneumatic unit. If a fuse blows, replace the fuse immediately.

* Refer to SP-50 Troubleshooting Manual for diagrams and instructions for replacement.
1. **REPORTING RESULTS**
	1. Adult Reference Range:

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Reference Range | Parameter | Reference Range |
| WBC: | 4.0-10.0 | NEUT% | 46-78 |
| RBC | male:4.50-5.90 | LYMPH% | 18-52 |
|  | female:4.00-5.20 | MONO% | 3-10 |
| HGB | male:13.5-17.5 | EO% | 0-6 |
|  | female:12.0-16.0 | BASO% | 0-3 |
| HCT | male:42-54 | IG% | 0-1.5 |
|  | female:37-47 | NRBC% | 0 |
| MCV | male:82-103 | NEUT# | 1.2-6.5 |
|  | female:82-103 | LYMPH# | 1.2-3.4 |
| MCH: | 26-34 | MONO# | 0.1-0.6 |
| MCHC: | 30-37 | EO# | 0.0-0.7 |
| RDW-CV: | 11.5-14.5 | BASO# | 0.0-0.2 |
| RDW-SD: |  | IG# | 0.0-0.11 |
| MPV: | 7.4-10.4 | NRBC# | 0 |
| PLT: | 150-399 |  |  |
|  |  | RET% | 0.5-1.5 |
| IPF% |  | RET# |  |
| IPF# |  | IRF |  |
|  |  | RET-H*e* |  |

* 1. Pediatric Reference Range:

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Reference Range | Parameter | Reference Range |
| WBC: | 4.0-12.0 | NEUT% | 42-75 |
| RBC | 4.00-5.30 | LYMPH% | 25-50 |
| HGB | 11.5-14.5 | MONO% | 2-9 |
| HCT | 33.0-43.0 | EO% | 0-10 |
| MCV | 76.0-90.0 | BASO% | 0-2 |
| MCH: | 25.0-31.0 | IG% | 0-1.5 |
| MCHC: | 32.0-36.0 | NRBC% | 0 |
| RDW-CV: | 11.5-15.0 | NEUT# | 1.2-6.5 |
| RDW-SD: |  | LYMPH# | 1.2-3.4 |
| MPV: |  | MONO# | 0.1-0.6 |
| PLT: | 130-400 | EO# | 0.0-0.7 |
|  |  | BASO# | 0.0-0.2 |
| IPF% |  | IG# | 0.0-0.12 |
| IPF# |  | NRBC# | 0 |
| RET% |  |  |  |
| RET# |  |  |  |
| IRF |  |  |  |
| RET-H*e* |  |  |  |

* 1. Acceptable Reporting Format: ***Complete this section with your laboratory’s reporting format. This may include rounding off criteria and acceptable units.***

**IX. REPORTING ABNORMAL RESULTS TO PHYSICIANS**: *All critical results must be called to a doctor or nurse and documented in Soft. Make sure the Critical Value has been verified and that the RBTO comment* ***“Critical result for (Test result) called to (R.N.) w/RBTO”*** *has been entered into the LIS system when the call is completed to the person responsible for the called “to” information.*

**X. LIMITATIONS OF PROCEDURE**

1. 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 |
| WBC-BF | 0.003 – 10.000 | x103/μL |
| RBC-BF |  0.002 – 5.000 | x106/μL |
| TC-BF# | 0.003 – 10.000 | x103/μL |

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. CELLPACK DCL should be used as the diluent. *Do not use CELLPACK DST for dilutions.*
3. Note the use of dilution for linearity on the patient report.
4. **Possible Sample Interferences** (For additional information, reference the analyzer *Instructions for Use*, *Flagging Guides, and Clinical Case Reports* located on the CRC).
5. Specimens must be free of clots and fibrin strands.
6. 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.
7. 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.
8. 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.
9. Extremely elevated WBCs may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values.
10. Severely hemolyzed samples (*in vitro*) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
11. 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.
12. Abnormal paraproteins found in Multiple Myeloma patients can falsely increase the HGB. To correct HGB perform plasma replacement.
13. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK DCL.
14. Rocking specimen excessively may affect the white cell membranes and cause false interpretive flags and messages.
15. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.
16. Body Fluid analysis: Failure to clear [Analysis result is high] may result in error of body fluid analysis.
17. **Flagging and Action Messages**

Abnormal samples on the XN-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 (eg., 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.**

**XI. PROCEDURAL NOTES AND CALCULATIONS**

A. If making a dilution of a patient specimen and running in XN Whole Blood mode or Body

 Fluid mode, multiply the parameters by the dilution factor. CELLPACK DCL should be

 used as the diluent. **Do not use** CELLPACK DST.

B. If correcting the HGB or HCT due to interfering substances, recalculate and correct the

 affected indices:

1. MCHC = HGB / HCT x 100

 2. MCH = HGB / RBC x 10

 3. MCV = HCT / RBC x 10

C. Use the Help function on the SP-50 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-50, Maintenance, Settings, and Shutdown

 functions are not available.

F. Current settings for XN and SP-50 should be recorded and maintained in the XN-Series

 Resource Manual and the SP-Series Implementation Manual.

G. 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.

H**. Do not** place samples on a mechanical rocker. Excessive mixing may alter white cell

membranes resulting in false interpretive flags and messages.

* 1. For troubleshooting specifics refer to the Sysmex XN-9100 *Instructions for Use or* SP-50 *Instructions for Use.*

## XII. REFERENCES

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2. Sysmex XN series *Administrator’s Guide* (North American Edition), Sysmex Corporation, Kobe, Japan.
3. Sysmex SP-50 *Instructions for Use [3 volumes]* (North American Edition), Sysmex Corporation, Kobe, Japan.
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1. Release Information, CellaVision® Body Fluid and Advanced RBC Applications.
2. *BeyondCareSM* Quality Monitor Instructions for Use
3. *BeyondCareSM* Quality Monitor Inspection Guide
4. XN Series Influence of Interfering Material on Hematology Parameters, Document

 Number: 1028-MKT

1. Soldin, SJ, Brugnara C., Wong EC. *Pediatric Reference Intervals*, AACC Press

Sysmex XN-9100, SP-50, DI-60, CF-70, RU-20, CELLCLEAN AUTO, CELLPACK DCL, DST, DFL, CELLSHEATH (CCS), CELLSHEATH (C), FLUOROCELL, LYSERCELL, XN CHECK, XN CHECK BF, XN CAL, XN CAL PF, BCQM*h*. and Sysmex ***Insight*** are trademarks of the Sysmex Corporation.