1. **PRINCIPLE**

The Sysmex XN-3100 is an integrated system that incorporates two hematology analytical modules as well as an automated slidemaker/stainer. 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.

The Sysmex SP-50 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. **(Shoreline and South campus only).**

The system 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**

**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
    4. 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
       4. Open micro tube - 110 μL minimum sample volume, 38 μL 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. Alcohol prep pads, isopropyl. Used to clean SP-50 spreader glass
      10. Methanol, anhydrous. Used to clean stain compartments
      11. Grey storage magazines (for storing slides processed from the SP-50)
      12. 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 DST 60 Days

CELLPACK DFL 60 Days

SULFOLYSER 60 Days (1.5L)

90 Days (5.0L)

Lysercell WNR 60 Days

Fluorocell WNR 90 Days

Lysercell WDF 90 Days

Fluorocell WDF 90 Days

Fluorocell RET 90 Days

Fluorocell PLT 90 Days

**SP REAGENTS**

Stain – Wright or Wright Giemsa

[INSERT LABORATORY SELECTED STAIN HERE]

Buffer – pH 6.6 – 7.2

[INSERT LABORATORY SELECTED BUFFER HERE]

Methanol, anhydrous (99.9%)

[INSERT LABORATORY SELECTED METHANOL HERE]

CELLPACK DCL 60 Days

* 1. **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.

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.

* + 1. CELLPACK DST (DST): Concentrated diluent of reagent for use in hematology analyzers.

CELLPACK DST Storage

1. Store at 2o-35oC away from direct sunlight.
2. If frozen, thaw and mix thoroughly before using.
3. CELLPACK DST is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.

CELLPACK DST 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 DST does not have ingredients with those characteristics.

* + 1. 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. **Stain / Buffer for SP-50 (Shoreline and South campus only)**
     1. Romanowsky stain (Wright or Wright-Giemsa)
        1. Used to fix and stain blood cells for the purpose of differentiation and morphologic evaluation

[INSERT MANUFACTURER INFORMATION HERE]

* + 1. Phosphate Buffer pH 6.6 – 7.2

[INSERT MANUFACTURER INFORMATION HERE]

**WARNING:** Stain contains methanol. 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. **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 staining pre-fix and cleaning of the spreader glass

[INSERT MANUFACTURER INFORMATION HERE]

**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. **Deionized water**

pH ~7.0 [LIST SOURCE HERE – Lab system or Vendor]

* 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

* 1. 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.

* + - 1. 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]
           + 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 CELLPACK DST with an RU-20

*Instructions for replacing CELLPACK DST are located in the*

*RU-20 CLSI guideline*

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.
     1. **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
3. Load the new reagent using a clean technique. Avoid placing spout kits or sensors on a contaminated surface
4. Input the new reagent information using either of the following procedures
5. Input the reagent code using a handheld barcode scanner
6. Manually enter the reagent code
   * + Touch the name of the reagent to be replaced in the [Replace Reagent] dialog box
     + Select the [Replace the Reagent] checkbox
     + Enter the [Reagent code] and touch [OK].

***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 seed immediate medical attention. If swallowed, seek medical advice immediately.
* Before use, please read the safety data sheet carefully.

**Document all reagent changes on the appropriate log.**

1. **CALIBRATION and PRECISION**

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

The laboratory must verify calibration 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 X-Barmy QC data, proficiency testing results and patient control testing results. The operator may calibrate the following parameters using XN CAL and XN CAL PF calibrator: WBC, RBC, HGB, HCT, PLT, PLT-F and RET.

**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.
2. **Calibration – XN CAL 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
14. The results are displayed in the [Calibrator Calibration (PLT-F)] analysis dialog box.
15. 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.
16. When all analysis results satisfy the conditions, select [Calibration] in the dialog box.
17. Select [OK] to display results in the [Calibrator Calibration (PLT-F)] execution dialog box.
18. 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. Quality control should be run in accordance to licensing agency regulations. It should be noted that for troubleshooting purposes, additional control runs may be necessary. 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. (**Shoreline and South campus only)**

1. **XN CHECK** 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 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**

***Complete this section with your laboratory’s policy for commercial and patient control analysis and review frequency.***

XN CHECK control levels: \_\_\_\_\_\_\_\_ will be run on 1st shift.

XN CHECK control levels: \_\_\_\_\_\_\_\_ will be run on 2nd shift.

XN CHECK control levels: \_\_\_\_\_\_\_\_ will be run on 3rd shift.

SP-50 QC slide will be evaluated daily on \_\_\_\_\_\_\_\_ shift.

The supervisor reviews commercial and X-Barmy charts every \_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**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. 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, selected per lab policy QC protocol, 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.
19. **Follow laboratory protocol for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability. Complete this section with your laboratory’s QC action plan for out of range commercial control products and X-bar.**
20. **Quality Control Management**
21. From the QC Chart view, select the [Manage] button on the toolbar.
22. Specify whether a QC run should be excluded from quality control
23. Select [Not Manage] to exclude data from the following:
24. Statistical computations (SD, Mean, CV)
25. Variable target computation
26. Number of data points = n
27. 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.
28. A comment may be added to the QC data selected by the cursor
29. Select [Input Any Comment] to input a free text comment.
30. Select [Fixed Comments] to use a comment from a list of preset comments in the QC settings menu.
31. Select [OK]
32. A comment bubble will be displayed when a comment exists for a QC run.
33. The comment will be visible in the comment display area when the cursor is placed on the QC run.
34. **Recording and Storage of QC Data**

Complete this section with your laboratory’s policy for documenting and retaining commercial controls and X-bar data.

1. Printing and saving QC Data
2. Select QC Files Icon and highlight file to output.
3. Select QC Chart Icon
4. Set Range of points to output by clicking [Range] and capturing the points with the cursors
5. Select [output] to print the selected chart to either GP or LP
6. Select [file] to save the data to removable media
7. **SP-50 Daily QC Slide Review (Shoreline and South campus only)**
8. Review the blood smears macroscopically for acceptability:
9. Smears are sufficient length (greater than half the length of the unfrosted portion of the slide).
10. The feathered edge becomes gradually thinner without streaks, holes, or tails.
11. Even, consistent staining of blood smear.
12. Review the blood smears microscopically for acceptability:
13. Relatively even distribution of cellular elements.
14. Acceptable morphology within the working area.
15. None or very little artifact of the cell morphology, (e. g., “punched-out” RBC’s, smashed WBC’s).
16. None, or very little stain precipitate or debris
17. 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 PLAT’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**

1. ***Insight*TM** Quality Assurance Program (QAP)

(The ***Insight*** program is for XN analyzers only)

Complete this section with your lab’s account #, analyzer serial #’s, responsible party for sending data (if no SNCS™ connection is available for up-to-the-minute submission) reviewing results and ***Insight*** reports. If your 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***.

The ***Insight*** account number is

The XN serial # is , and SN#

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. X-barM Moving Patient Averages
2. Establishing X-barM Limit%
3. State how your lab established targets and limits for X-barM. The Sysmex data center suggests using 200 data points representing 4000 samples in 20 patient size batches. Data will be collected over multiple reagent lots and over at least one month including all types of patient samples normally encountered.
4. Batch size and review frequency
5. Complete this section with your lab’s batch size and chart review frequency. X-barM can be monitored in lieu of a retained patient sample for a longitudinal control if 100 or more patients are run each day. Common batch size is 20; however, the Sysmex data center suggests using a larger batch size to allow about six points to be plotted per 24 hour period. Include when and whether X-barM will be turned off for specific groups of patient specimens to avoid QC error messages related to population shifts.

Our batch size for X-barM is patient samples per batch. Each point on the X-barM graph represents one batch.

Supervisor will review X-barM charts every days.

1. Activating / deactivating X-barM Control
2. Select the analyzer menu button on the control menu
3. Select X-barM Setting
4. Click [Execute] to perform X-barM Control, Click [Cancel] to deactivate.
5. Click [OK]
6. **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

* + - 1. If applicable, verify waste container is empty
      2. Verify network / host connections are properly working
      3. Ensure that the 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. Empty waste tanks (if applicable)
      3. Ensure empty grey magazines are loaded onto the SP-50 feed out block
      4. Ensure that all power switches are on the “on” positions
    1. Press and release the green master switch on the XN-3100 & XN-2000 sampler unit
       1. The status indicator LED will flash green
       2. The XN-IPU will automatically turn on
       3. The SP-50 will begin start-up
       4. 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 user

* + - 1. Each XN analyzer will begin start-up
    1. The XN screen will display the logon

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

**SP-50**

1. Initialization of the mechanical parts
2. Rinsing of hydraulic unit
3. Replenishment of reagent

* + 1. 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. If smear is required, rack will be transported to SP-50 via analysis line and samples will be aspirated by SP-50.
       9. 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
       10. If no smears are required, rack will be transported to the left sampler pool without stopping at the SP-50.
       11. 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

The sampler for the analyzer, or the sampler for the SP-50 is separated from the transport line of the overall system and operated as a standalone device

* + - 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. SP-50 Manual Mode – [Smearing and staining] / [smearing only]

Use this procedure when you want to:

* Interrupt sampler preparation for an urgent sample
* Prepare smear only using a regular sample collection tube, micro collection sample tube, or RBT collection tube. ***Start from step [a] of this procedure***
* Prepare smear and staining on a regular sample collection tube, micro collection tube, or RBT collection tube. ***Start from step [f] of this procedure***

**NOTE**: When the SP-50 is in manual mode – the racks arriving from the XN will wait until the SP-50 sampler mode is in the ready state. The Mode Select switch on the sampler can be depressed so that all racks by-pass the SP-50 and will continue on to the left sampler pool

Er

1. Open the manual magazine holder cover
2. Pull out the left or right manual magazine holder
3. Load an empty magazine in the left or right manual magazine holder
4. Push in the manual magazine holder
5. Close the manual magazine holder cover
6. If the sample tube holder has not been ejected out, press the mode switch on the front of the main unit
7. Touch [select mode] in the status area. A dialog box will appear
8. Touch [smearing and staining] or [smearing only]
9. Touch [OK]. The dialog box closes
10. Touch manual in the status area to change the following smear preparation conditions
11. Touch [sample number] and manually enter the barcode or select the checkbox to read a sample barcode with the barcode reader of the main unit
12. Touch [set smear] to select the smear conditions according to the patient HCT.

* There are 8 levels pre-programmed in the software and 8 additional levels that can be assigned and programmed by the laboratory

1. Touch [set stain] to change the default stain profile
2. Touch [preparation action] to select/deselect the following actions

* [Alarm] when smear preparation is complete
* [Aspiration sensor] when volume of blood is small
* [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. Touch [Cap Open] if the sample tube has the ***cap removed***
2. Touch [RBT] if a Raised Bottom tube is used

**NOTE:** The option to select [Cap Open] will not be available to the user if the RBT tube is selected. If RBT is not selected, the instrument may be damaged

1. Touch [1st slide] / [2nd slide] to choose a glass slide from left or right slide supply cassette
2. Touch [OK] when complete with smear preparation edits
3. ***Mix the sample tube according to your laboratory protocol***

* If using a regular sample tube or an RBT tube type, insert the sample tube in the front tube holder
* If using a micro sample tube, insert the specimen in the micro collection sample tube holder (located behind the regular sample tube holder to the rear of the instrument)

**CAUTION:** Please remove the plastic cap from the micro sample tube before pressing the start switch. Otherwise the instrument may be damaged

1. Press the start switch on the main menu of the SP-50
2. The sample holder is retracted and smear preparation starts
3. When the sample aspiration is completed, the sample tube holder is ejected out forward automatically
4. Remove the tube from the tube holder
5. Press the mode switch on the main unit to return the instrument to sampler mode and retract the tube holder into the instrument
6. If the mode select switch on the sampler unit was selected to by-pass the SP-50, press the mode select switch again to return to on line analysis
7. Remove the prepared smears from the magazine
8. In [Smearing and Staining] mode, the magazine is fed to the magazine storage unit
9. In [Smearing Only] the magazine is fed out to the manual magazine holder
   * 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 or bone marrow specimens that were prepared manually

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 sampler 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 sampler to return the analyzer to “on line” mode
15. Remove the prepared smears from the manual magazine holder
16. **MAINTENANCE**
17. **Daily**
18. Shutdown

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

1. Shutdown entire system – Sampler Mode
2. Confirm analyzers, sampler unit and SP-50 are at ready
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 2 empty racks
   * Place one tube of CELLCLEANAUTO in a rack, position 8. This rack will shut down the SP-50

***NOTE:***

* Either Shutdown1 or Shutdown2 can be performed on the SP-50 in the sampler mode.
* The frequency of Shutdown2 is determined by the analyzer settings or if more than 40 days has passed since the last Shutdown 2 was performed.
* See SP-50 Basic Operation for detailed instructions
  + - * + Place 2 tubes of CELLCLEAN AUTO in rack two, positions 9 and 10. This rack will shut down the XNs.

***CAUTION:***

* Use 1 vial of CELLCLEAN AUTO for each instrument. Do not reuse CELLCLEAN AUTO that has previously been used
* During Shutdown, other sample tubes are not accepted

1. Load the racks onto the right sampler pool (analyzer side)
2. Shutdown is performed automatically
3. The analyzers and the IPU will automatically power off once the Shutdown sequence is complete (approximately 15 minutes)
4. Remove the glass slide used for cleaning in the manual magazine holder on the SP-50
5. Remove the rubes of CELLCLEAN AUTO from the racks
6. XN and SP-50 on-board maintenance will auto-populate
7. Shutdown individual analyzers – sampler mode
8. Confirm the analyzer to be shutdown is in the ready mode
9. Confirm tube holders are retracted are retracted into the analyzers
10. Confirm glass sides are loaded and there is sufficient reagent on the SP-50
11. Obtain an empty rack

* Place one tube of CELLCLEAN AUTO in position 10 if the right XN is to be cleaned
* Place one tube of CELLCLEAN AUTO in position 9 if the left XN is to be cleaned
* Place on tube of CELLCLEAN AUTO in position 8 if the SP-50 is to be cleaned

NOTE:

* Either Shutdown1 or Shutdown2 can be performed on the SP-50 in the sampler mode.
* The frequency of Shudown2 is determined by the analyzer setting or if more than 40 days has passed since the last Shutdown2
* See SP-50 Basic Operation for detailed instructions.

1. Load the rack onto the right sampler pool (analyzer side)
2. Shutdown is performed automatically on the analyzer dedicated to the tube position

* The SP-50 will automatically power off after Shutdown is complete
* The XN will ***NOT*** power off after Shutdown is complete

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

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. Remove the tube of CELLCLEAN AUTO from the rack and discard
2. Shutting down the sampler

If the separate shutdown procedures for the XN’s have already been completed, you can turn OFF the sampler unit

1. Hold down the green start-up switch on the sampler for at least 3 seconds

until the status LED light turns off

1. The sampler power is turned on

5) Shutdown1– 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

* You may 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. Empty waste container (if applicable)

**CAUTION – RISK OF INFECTION**

* Be sure to wear adequate personal protective equipment, such as protective gloves, a protective mask, protective eyewear, and a lab coat when working. Wash your hands after completing the task

Empty the waste container daily or when the HELP dialog box appears [Waste containers full]

1. Prepare an empty waste fluid tank and remove the cap
2. Remove the cap from the waste fluid tank that has become full. Pull the float switch and tubing from the bottle
3. Insert the float switch and tubing into the new waste fluid tank
4. Secure the cap
5. If the HELP dialog box appeared, touch [Execute]. The error will clear and the dialog box will close
6. Inspect the Staining Pool – SP-50

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, 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. Open the staining part cover
2. Open the staining pool cover forward and down, and lift and remove the 2 staining pools

* use a lint free lines 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. place the stain pools in a container used for cleaning
2. with a squeeze bottle filled with methanol, spray each stain pool with methanol and wipe dry with a lint free cloth or gauze
3. reinstall the staining pools taking care to replace each pool in their proper placements
4. replace the staining pool cover and close the staining part cover
5. **Weekly Maintenance**
6. 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. [This procedure can be performed via sampler or manual modes.]

* 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 has passed since the last Shutdown2

**NOTE**: Please refer the SP-50 Basic Operation Manual – Chapter 5 – Instrument Settings for additional information on programming the frequency of Shutdown2 settings.

1. Clean the Staining Pool

The stain pool may collect a buildup of stain precipitate. When [Shutdown2] is completed, 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

In the con

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

* 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. Install the 2 staining pools
4. Replace staining pool covers and close the staining part cover
5. Clean Rinse Bottles

If re-usable container for deionized water and/or buffer are used, empty and clean weekly

1. Unscrew the cap of the rinse container, remove the tubing and empty the contents
2. Rinse the container with methanol and allow to dry
3. Fill container with fresh deionized water or buffer
4. Check the pH of the deionized water before using the analyzer
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 LAED 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
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
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. **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*
2. **REPORTING RESULTS**

Reference Ranges are reported with every result. Please refer to Table: R-H-10-?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| **ANALYTE** | **AGE** | **NORMAL RANGE BOTH SEXS** | **MALE** | **FEMALE** | **UNITS** |
|  |  |  |  |  |  |
| ***WBC*** | < 1 DAY | 9.0-30.0 |  |  | X10~3 uL |
|  | 1D-6D | 9.0-34.0 |  |  | X10~3 uL |
|  | 7D-13D | 5.0-21.0 |  |  | X10~3 uL |
|  | 14D-29D | 5.0-20.0 |  |  | X10~3 uL |
|  | 1M-11M | 5.0-19.5 |  |  | X10~3 uL |
|  | 1YR-1YR 11M | 6.0-17.5 |  |  | X10~3 uL |
|  | 2YR-3YR 11M | 6.0-17.0 |  |  | X10~3 uL |
|  | 4YR-5YR 11M | 5.5-15.5 |  |  | X10~3 uL |
|  | 6YR-7YR 11MO | 5.5-14.5 |  |  | X10~3 uL |
|  | 8YR-15YR 11MO | 4.5-13.5 |  |  | X10~3 uL |
|  | 16YR-17YR 11MO | 4.5-13.0 |  |  | X10~3 uL |
|  | ADULT | 4.8-10.8 |  |  | X10~3 uL |
|  |  |  |  |  |  |
| ***RBC*** | 0-2 DAYS | 3.90-5.50 |  |  | X10~6/uL |
|  | 3- 6DAYS | 4.00-6.60 |  |  | X10~6/uL |
|  | 7-13 DAYS | 3.90-6.30 |  |  | X10~6/uL |
|  | 14-29 DAYS | 3.60-6.20 |  |  | X10~6/uL |
|  | 1MO -59 DAYS | 3.00-5.40 |  |  | X10~6/uL |
|  | 2MO-5MO | 2.70-4.90 |  |  | X10~6/uL |
|  | 6MO-23MO | 3.70-5.30 |  |  | X10~6/uL |
|  | 2YR-5YR | 3.90-5.30 |  |  | X10~6/uL |
|  | 6YR-11YR | 4.00-5.20 |  |  | X10~6/uL |
|  | 12YR-17YR |  | 4.50-5.30 | 4.10-5.00 | X10~6/uL |
|  | 18-20 |  | 4.50-5.20 | 4.00-5.20 | X10~6/uL |
|  | ADULT |  | 4.70-6.10 | 4.20-5.40 | X10~6/uL |
|  |  |  |  |  |  |
| ***HGB*** | 0-2 DAYS | 13.5-19.5 |  |  | g/dL |
|  | 3- 6DAYS | 14.5-22.5 |  |  | g/dL |
|  | 7-13 DAYS | 13.5-21.5 |  |  | g/dL |
|  | 14-29 DAYS | 12.5-20.5 |  |  | g/dL |
|  | 1MO -59 DAYS | 10.0-18.0 |  |  | g/dL |
|  | 2MO-5MO | 9.0-14.0 |  |  | g/dL |
|  | 6MO-23MO | 10.5-14.5 |  |  | g/dL |
|  | 2YR-5YR | 11.5-13.5 |  |  | g/dL |
|  | 6YR-11YR | 11.5-15.5 |  |  | g/dL |
|  | 12YR-17YR |  | 13.0-16.0 | 12.0-16.0 | g/dL |
|  | 18-20 |  | 13.5-17.5 | 12.0-16.0 | g/dL |
|  | ADULT |  | 14.0-18.0 | 12.0-16.0 | g/dL |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| ***HCT*** | 0-2 DAYS | 42-60 |  |  | % |
|  | 3- 6DAYS | 45-67 |  |  | % |
|  | 7-13 DAYS | 42-66 |  |  | % |
|  | 14-29 DAYS | 39-63 |  |  | % |
|  | 1MO -59 DAYS | 31-55 |  |  | % |
|  | 2MO-5MO | 28-42 |  |  | % |
|  | 6MO-23MO | 33-39 |  |  | % |
|  | 2YR-5YR | 34-40 |  |  | % |
|  | 6YR-11YR | 35-45 |  |  | % |
|  | 12YR-17YR |  | 37-49 | 36-46 | % |
|  | 18-20 |  | 41-53 | 36-46 | % |
|  | ADULT |  | 42-52 | 37-47 | % |
|  |  |  |  |  |  |
| ***MCV*** | 0-2 DAYS | 98-118 |  |  | fL |
|  | 3- 6DAYS | 95-121 |  |  | fL |
|  | 7-13 DAYS | 88-126 |  |  | fL |
|  | 14-29 DAYS | 86-124 |  |  | fL |
|  | 1MO -59 DAYS | 85-123 |  |  | fL |
|  | 2MO-5MO | 77-115 |  |  | fL |
|  | 6MO-23MO | 70-86 |  |  | fL |
|  | 2YR-5YR | 75-87 |  |  | fL |
|  | 6YR-11YR | 77-95 |  |  | fL |
|  | 12YR-17YR |  | 78.98 | 78-102 | fL |
|  | 18-20 |  | 80-100 | 80-100 | fL |
|  | ADULT |  | 80-94 | 81-99 |  |
|  |  |  |  |  |  |
| ***MCH*** | 0-6 DAYS | 31-37 |  |  | pg |
|  | 7-59 DAYS | 28-40 |  |  | pg |
|  | 2MO-5MO | 26-34 |  |  | pg |
|  | 6MO-23MO | 23-31 |  |  | pg |
|  | 2YR-5YR | 24-30 |  |  | pg |
|  | 6YR-11YR | 25-33 |  |  | pg |
|  | 12YR-17YR | 25-35 |  |  | pg |
|  | ADULT | 26-34 |  |  | pg |
|  |  |  |  |  |  |
| ***MCHC*** | 0-2 DAYS | 30-36 |  |  | g/dL |
|  | 3- 6DAYS | 29-37 |  |  | g/dL |
|  | 7-29 DAYS | 28-38 |  |  | g/dL |
|  | 1MO-5M0 | 29-37 |  |  | g/dL |
|  | 6MO-23MO | 30-36 |  |  | g/dL |
|  | 2YR-ADULT | 31-37 |  |  | g/dL |
|  |  |  |  |  |  |
| ***RDW*** | ALL |  | 35.1-43.9 | 36.4-46.3 | fL |
| ***PLT*** | ALL | 130-400 |  |  | X10~3 uL |
|  |  |  |  |  |  |
| ***MPV*** | ALL | 7.4-10.4 |  |  | fL |

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 % |

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 (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**

1. **REFERENCES**
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4. Sysmex SP-50 *Instructions for Use [3 volumes]* (North American Edition), Sysmex Corporation, Kobe, Japan.

* Basic Operation
* General Instructions
* Troubleshooting

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