Sysmex XN-2000

COMPLETE BLOOD COUNT OF WHOLE BLOOD

ON THE SYSMEX®XN-2000

I. Principle

The Sysmex XN-2000 is an integrated system that incorporates two hematology analytical modules in a single compact configuration.

The XN-Series module 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 is useful in the diagnosis of disease states such as anemias, leukemias, and allergic reactions, and viral, bacterial, and parasitic infections.

The analyzer performs hematology analysis according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (semiconductor laser), and SLS-hemoglobin methods.

The device counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection. Hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin (HGB) is converted to SLS-hemoglobin and read photometrically.

The white blood cell (WBC) count, differential (DIFF), reticulocytes (RET), nucleated red blood cells (NRBC), and fluorescent platelets (PLT-F) are all evaluated using flow cytometry with a semiconductor laser exploiting the differences in cell size, complexity, and RNA/DNA content. Forward Scattered Light provides information on blood cell size and Lateral Scattered Light provides information on the cell interior such as the size of the

nucleus. Lateral Fluorescent Light intensity increases as the concentration of the stain becomes higher. By measuring the intensity of the fluorescence emitted, information is obtained on the degree of blood cell staining. Fluorescent light is emitted in all directions. The XN detects the fluorescent light that is emitted sideways.

II. Specimen

A. Required specimen

1. Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.
2. Serous and Synovial fluids should be collected in EDTA-2K anticoagulant.
3. The use of anticoagulant with CSF specimens is neither required nor recommended.
4. Sodium Citrate may be used when EDTA platelet clumping or platelet satellitism is noted on the EDTA specimen. Use Sodium Citrate results for platelet counts and WBC counts and for MPV. Multiply instrument PLT and WBC result by 1.11 to correct for anticoagulant dilution. Do not multiply the MPV.

B. Specimen volumes required

1. Optimal draw is a tube drawn to capacity. The collection tube should be filled to a minimum of one-half full for acceptable results. EXCEPTION: a 2.5mL EDTA tube filled less than one-half full is unacceptable.
2. A minimum of 1mL of whole blood is required for auto-sampler mode analysis.
3. Minimum volume required for manual analysis in whole blood mode:
   a) Closed tube – 1mL
   b) Open tube – 300µL
   c) Open microtube – 160µL
4. Minimum volume required for manual analysis in body fluid mode:
   a) Closed tube – 1mL
   b) Open tube – 300µL
   c) Open microtube – 160µL
5. An EDTA micro-container filled above the 250µL line is adequate for testing in the manual mode. If testing in the manual mode or repeat testing will be needed a microtainer should be filled to 500µL. For repeat testing the manual mode should be used. If quantity is not sufficient for repeat testing a redraw should be requested.

C. Unacceptable specimens listed below must be redrawn:

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 site.

D. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins.

E. Stored Specimen Stability

1. Stored at 4-8^{o}C, EDTA blood samples with normal results may be analyzed up to 48 hours without

significant loss of differential stability.

2. Sample stability at room temperature is 24 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours. This may be minimized by refrigeration.
3. Allow refrigerated samples to come to room temperature and mix well before analysis.
4. Do not place samples on a mechanical rocker. Constant rocking may cause platelet clumping and alter white cell membranes, resulting in false interpretive messages. If handling older refrigerated specimens, allow to warm to room temperature and resuspend by gently rocking by hand before placing on the analyzer.

III. Supplies and Reagents

A. Supplies

1. Lint-free plastic lined lab wipes
2. Gauze
3. Test tubes
4. Plastic squeeze bottles
5. CELLCLEAN™ Auto
6. Sysmex Reagents
7. Commercial Controls; XN CHECK ™, XN CHECK™ BF

B. Sysmex™ Reagent information

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.

C.

REAGENT	OPEN EXPIRATION
CELLPACK DCL	60 days
CELLPACK DST	60 days
CELLPACK DFL	60 days
SULFOLYSER (1.5L)	60 days
SULFOLYSER (5.0L)	90 days
Lysercell WNR	60 days
Fluorocell WNR	90 days
Lysercell WDF	90 days
Fluorocell WDF	90 days

Fluorocell RET	90 days
Fluorocell PLT	90 days

D. Diluents

1. **CELLPACK DCL**: Whole blood diluent for use in hematology analyzers.

CELLPACK DCL Storage

a) Store at 2°-35°C away from direct sunlight.

b) If frozen, thaw and mix thoroughly before using.

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

CELLPACK DCL Stability

d) Unopened: stable until expiration date printed on the container.

e) Opened: stable for 60 Days.

CELLPACK DCL Hazard Risk

f) The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens.CELLPACK does not have ingredients with those characteristics.

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

CELLPACK DST Storage

a) Store at 2°-35°C away from direct sunlight.

b) If frozen, thaw and mix thoroughly before using.

c) CELLPACK DST is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.

CELLPACK DST Stability

d) Unopened: stable until expiration date printed on the container.

e) Opened: stable for 60 Days.

CELLPACK DST Hazard Risk

f) 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.

3. **CELLPACK DCL (DCL):**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 DCL Storage

a) Store at 2°-35°C away from direct sunlight.

b) Do not use the reagent if it is suspected to have been frozen.

c) Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

CELLPACK DCL Stability

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

e) Opened, it is stable for 60 Days.

CELLPACK DCL Hazard Risk

f) 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.

E. Lyse Reagents

1. **SULFOLYSER (SLS):** Reagent for the automated determination of hemoglobin concentration of blood. Sulfolyser is lysing reagent that releases the hemoglobin to be measured by the SLS hemoglobin method.

SULFOLYSER Storage

a) Store at 1°-30°C away from direct sunlight.

b) Allow the container to equilibrate to environmental temperature (15-30°C) prior to use.

c) Do not use the reagent if it is suspected to have frozen.

d) Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

SULFOLYSER Stability

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

f) Opened, it is stable for 60 Days (1.5L) or 90 Days (5L).

SULFOLYSER Hazard Risk

g) 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.

2. **LYSECELL 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

a) Store at 2°-35°C away from direct sunlight.

b) Allow the container to equilibrate to environmental temperature (15-30°C) prior to use.

c) Do not use the reagent if it is suspected to have frozen.

d) Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

LYSERCELL WNR Stability

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

f) Opened, it is stable for 60 Days.

LYSERCELL WNR Hazard Risk

g) 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.

3. **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

a) Store at 2°-35°C away from direct sunlight.

b) Allow the container to equilibrate to environmental temperature (15-30°C) prior to use.

c) Do not use the reagent if it is suspected to have frozen.

d) Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

LYSERCELL WDF Stability

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

f) Opened, it is stable for 90 Days.

LYSERCELL WDF Hazard Risk

g) 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.

F. 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

a) Store at 2°-35°C in a dark place.

b) Do not use the reagent if it is suspected to have frozen.

FLUOROCELL WNR Stability

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

d) Opened, stable for 90 Days.

FLUOROCELL WNR Hazard Risk

e) 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. Fluorocell WNR does not have ingredients with those characteristics.

2. **FLUOROCELL WDF:** Used to stain the leukocytes in diluted and lysed blood samples for determination of differential count in blood.

FLUOROCELL l WDF Storage

a) Store at 2°-35°C in a dark place.

b) Do not use the reagent if it is suspected to have frozen.

FLUOROCELL WNR Stability

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

d) Opened, stable for 90 Days.

FLUOROCELL WNR Hazard Risk

e) 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. Fluorocell WDF does not have ingredients with those characteristics.

3. **FLUOROCELL RET:** Used to stain the reticulocytes in diluted blood samples for the assay of

reticulocyte count, reticulocyte percent in blood.

FLUOROCELL RET Storage

a) Store at 2°-35°C in a dark place.

b) Do not use the reagent if it is suspected to have frozen.

FLUOROCELL RET Stability

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

d) Opened, stable for 90 Days.

FLUOROCELL RET Hazard Risk

e) 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. Fluorocell RET does not have ingredients with those characteristics.

4. **FLUOROCELL PLT:** Used to stain the platelets in diluted blood samples for the assay of platelet counts in blood.

FLUOROCELL PLT Storage

a) Store at 2°-35°C in a dark place.

b) Do not use the reagent if it is suspected to have frozen.

FLUOROCELL PLT Stability

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

d) Opened, stable for 90 Days.

FLUOROCELL PLT Hazard Risk

e) 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.

G. Cleaning Agent

1. **CELLCLEAN AUTO:** Detergent for fully automated hematology analyzer. A strong alkaline detergent used to remove lysing reagents, cellular residuals, and blood proteins remaining in the hydraulics of the analyzer.

CELLCLEAN AUTO Storage

a) Store at 1-25°C, away from direct sunlight.

b) Do not use the reagent if it is suspected to have frozen.

CELLCLEAN AUTO Stability

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

H. Commercial Control Material for XN analyzers

1. XN CHECK™

a) Manufactured by Streck; available as a tri-level package.

b) Whole blood commercial control used to monitor performance of the XN analyzers.

c) Formulation

(a) Consists of human red and white blood cells with a platelet component suspended in fluid medium.

(b) Each vial contains 3 mL of control material.

d) Storage

(a) Store vials at 2-8˚C

(b) Do not freeze or expose to excessive heat.

e) Stability

(a) Unopened and properly stored, XN CHECK™ is stable until the expiration date printed on the unopened vial.

(b) Open vial stability is 7 days when promptly refrigerated after each use.

(c) Record the date on each vial upon opening or cap piercing.

f) 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.

g) If deterioration is suspected, call the Sysmex Technical Assistance Center. 1-888-879-7639 (1-888-8SYSMEX)

2. XN CHECK™ BF

a) Manufactured by Streck, available as a bi-level package.

b) Body Fluid commercial control used to monitor performance of the XN analyzer body fluid analysis mode.

c) Formulation

(a) Each vial contains 3 mL of control material.

d) Storage

(a) Store vials at 2-8˚C

(b) Do not freeze or expose to excessive heat.

e) Stability

(a) Unopened and properly stored, XN CHECK™ BF is stable until the expiration date printed on the unopened vial.

(b) Open vial stability is 30 days when promptly refrigerated after each use.

(c) Record the date on each vial upon opening or cap piercing.

f) 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 assay expected ranges after appropriate troubleshooting.

g) If deterioration is suspected, call the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX)

I. Calibrators

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

XN CAL™ Storage

a) Store the calibrator in a dark refrigerator at 2-8°C.

XN CAL™ Stability

b) 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 CAL™ PF: for use in calibrating the analyzer for PLT-F (platelet count obtained from the PLT-F channel).

XN CAL™ PF Storage

a) Store the calibrator in a dark refrigerator at 2-8°C.

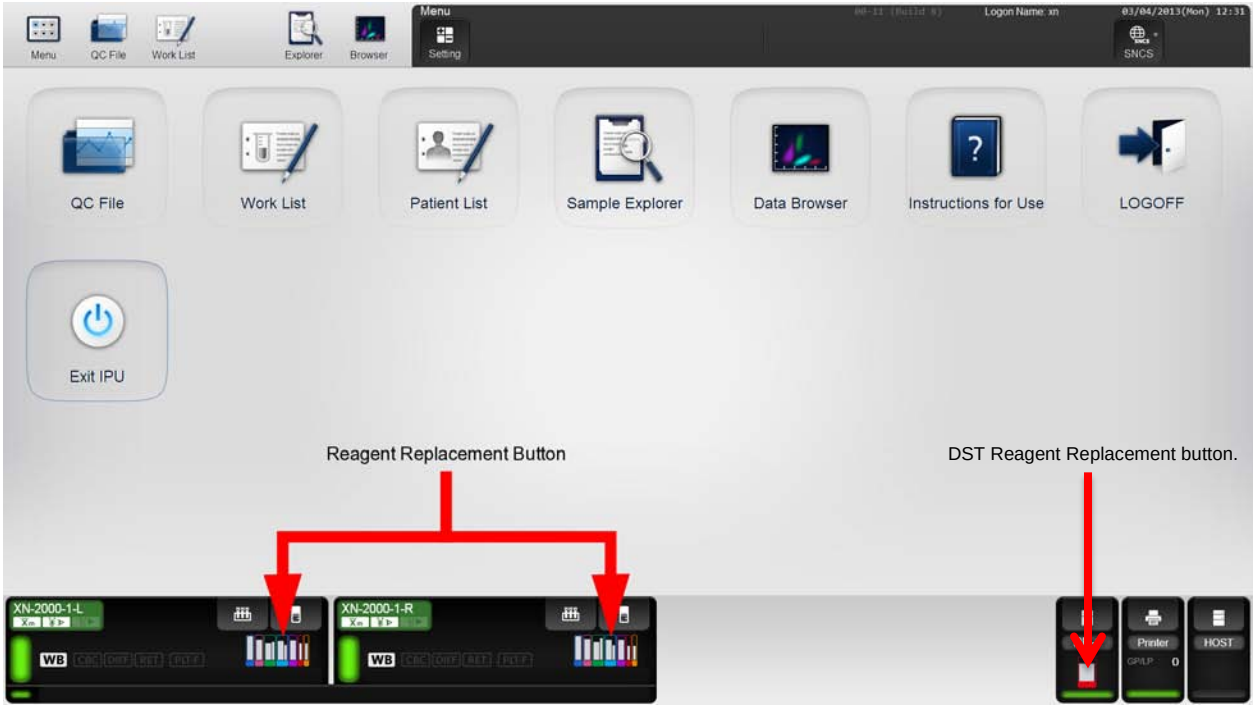
XN CAL™ PF Stability

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

c) Open vial stability is 4 hours.

IV. Reagent Replacement.

1. Press or click the Reagent Replacement Dialog button on the IPU monitor (see next page).



2. This will display the [Reagent Replacement] dialog box. Click on the box for the reagent to replace.

A. XN Diluent/Lyse Reagent Replacement

1. When the reagent runs out during analysis, the analysis is paused and an error message appears in the analyzer area of the Control menu.
2. Display the [Reagent Replacement] dialog box to replace the reagent.
   a) Select the help button on the control menu.
   b) Select [Execute]. Remaining Reagent Volume indicator appears.
3. Replacing a new diluent / hemolytic agent
   a) Display the [Reagent Replacement] dialog box.
   b) Confirm the reagent has not expired. Remove the cap from the new reagent container.
4. Input the reagent code (barcode)
   a) Place the cursor in the reagent code field.
   b) Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.
   c) Select [OK].
5. Remove the cap from the old reagent container.
6. Pull out the dispensing set straight up.
7. Insert the dispensing set into the new reagent container straight up.
8. Close the cap.
9. Select [Execute]. Reagent replacement starts. When complete, the dialog box closes automatically.

B. Replacing CELLPACK DST (on the RU-20).

NOTE: Enter barcode info through the reagent screens on the XN-2000, not the RU-20 unit.RU-20 unit must be on the main screen (below) when changing reagents. If it is not, press [return] until the main screen appears.

   a) Select the RU-1 reagent icon on the IPU screen (lower right).
   b) Select [Replace Reagent].
   c) Input the reagent code (barcode).
   d) Place the cursor in the reagent code field.

e) Scan the reagent code on the outer box of the new reagent with the XN-2000 hand-held barcode reader or manually enter the reagent code. Confirm that reagent has not expired.

f) Select [OK].

g) Remove the cap from the old reagent container.

h) Pull out the dispensing set straight up.

i) Remove the cap from the new reagent container. New reagent cube must be placed on the RU-20 unit.

j) Insert the dispensing set straight into the new reagent container.

k) Close the cap.

l) Select [Execute]. Reagent replacement starts. When complete, the dialog box closes automatically.

C. Replacing Dye

1. Prepare the new reagent cartridge. 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. When the dye 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.
   a) Make sure the color of the label on the new reagent cartridge matches the color of the dye cover and install. Analyzer will beep as confirmation of new reagent installation.
   b) 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.
   a) When the cover is pulled down, the Help dialog box closes automatically.
   b) The ID of the new reagent is read automatically and the information is registered.
7. Close the top front cover.
   a) Reagent replacement starts.
   b) When complete, the reagent replacement window closes automatically.

V. Calibration

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. In general, calibration will be performed by Sysmex Field Service as part of preventive maintenance.

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-barM QC data, proficiency testing results and patient control testing results.The operator may calibrate the following parameters using XN CAL™ and XN CAL™ PF calibrator:WBC, RBC, HGB, HCT, PLT, PLT-F and RET.

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

A. Precision Check

1. Perform routine maintenance on the analyzer and perform a background count to ensure counts are within acceptable limits.
2. Verify that there is sufficient volume of all reagents.Precision and Calibration procedures will be aborted if the XN runs out of reagent.
3. Obtain a sample of fresh normal whole blood. **Do not** use commercial controls or calibrators for precision.The blood donor specimen should:
4. Be from a healthy person who is not taking any medication,
5. Have a morphologically and numerically normal CBC,
6. Be drawn in potassium EDTA anticoagulant tube using proper collection technique,
7. Have a minimum of 2.5 mL of sample.
8. On the main unit, check the Status indicator LED.Confirm the LED is green indicating the analyzer is ready.
9. If the tube holder has not ejected, press the Mode Switch. 
10. Select the Change Analysis Mode button on the control menu and select Whole Blood

11. Select [OK] to close the dialog box

12. Select the Analyzer menu button on the control menu

13. Select [Calibration] – [Precision Check]

14. Mix the vial containing the sample – 10 end-over-end inversions confirming cell button is dispersed.

15. Place the vial in the sample tube holder.

16. Press the Start Switch on the analyzer.

    a) The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer.

    b) The tube holder will slide out when analysis is complete.

17. 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.

18. When all analysis results satisfy the conditions, select [OK] in the dialog box.

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

B. CALIBRATION – XN CAL™

1. On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready.

2. If the tube holder has not ejected, press the Mode Switch .

3. Select the Change Analysis Mode button on the control menu and select Whole Blood.

4. Select [OK] to close the dialog box.

5. Select the Analyzer menu button on the control menu.

6. Select [Calibration] – [Calibrator Calibration].

7. Mix the vial containing the calibrator according to the package insert.

8. Place the vial in the sample tube holder.

9. Press the Start Switch on the analyzer.

    a) The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer

    b) The tube holder will slide out when analysis is complete

10. The results are displayed in the [Calibrator Calibration] analysis dialog box.

11. If the analysis results to 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.

12. When all analysis results satisfy the conditions, select [Calibration] in the dialog box.
13. Select [OK] to display results in the [Calibrator Calibration] execution dialog box.
14. 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:
    a) 80% ≤New Rate ≤ 120%
    b) New Rate – Current Rate ≤+5
    c) Range Value ≤Max Range
    d) Acceptable Limit ≤ Delta Percent ≤ Service Limit
    e) 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.
    f) 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.
15. Select [OK] to update the compensation rates. The calibration process is logged in the calibrator calibration history.

C. CALIBRATION – XN CAL™ PF

1. On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready.
2. If the tube holder has not ejected, press the Mode Switch  .
3. Select the Change Analysis Mode button on the control menu and select Whole Blood.
4. Select [OK] to close the dialog box.
5. Select the Analyzer menu button on the control menu.
6. Select [Calibration] – [Calibrator Calibration (PLF-F)].
7. Mix the vial containing the calibrator according to package insert.
8. Place the vial in the sample tube holder.
9. Press the Start Switch  on the analyzer.
    a) The analysis is automatically performed 11 times consecutively with the tube holder pulled into the analyzer
    b) The tube holder will slide out when analysis is complete
10. The results are displayed in the [Calibrator Calibration (PLT-F)] analysis dialog box.
11. If the analysis results to 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.

12. When all analysis results satisfy the conditions, select [Calibration] in the dialog box.
13. Select [OK] to display results in the [Calibrator Calibration (PLT-F)] execution dialog box.
14. 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:
    a. 80% ≤New Rate ≤ 120%
    b. New Rate – Current Rate ≤+5
    c. Range Value ≤Max Range

    a) Acceptable Limit ≤ Delta Percent ≤ Service Limit

    b) 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.

    c) 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.
15. 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.

VI. QUALITY CONTROL

Quality control is performed in order to monitor an analyzer's performance over time.XN CHECK™and XN CHECK™BF are the materials 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.

A. XN CHECK™Commercial Controls Instructions for Use

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

B. XN CHECK™BF Commercial Body Fluid Controls Instructions for Use

1. Remove vials from refrigerator and allow them to come to room temperature (18 – 25°C) for approximately 15 minutes.
2. Mix vials by a minimum of 20 gentle end-to-end inversions. The cell button in the bottom of the vial must be completely suspended.

C. Frequency of Control use and review

All 3 control levels will be run on all shifts.

If daily cleaning or the weekly shutdown is performed, the QC should be run after completion.

XN CHECK™ BF control levels: L1 & L2 will be run once per shift if body fluid specimens to be tested.

Body fluid controls will be run in body fluid mode. See section E below.

The supervisor reviews commercial, patient, and **Xm**charts every month. Quality Control exceptions appear daily on the Exception Report. For more information refer to the Hematology Quality Management procedure.

D. 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
   a) Material
   b) Lot Number
   c) Expiration Date
6. 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

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.

E. XN CHECK™ QC Analysis

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

F. XN CHECK™ BF Analysis

1. Check the Status indicator LED on the analyzer to confirm analyzer is in ready state.
2. If the tube holder is not ejected, press the Mode Switch. Tube holder will slide out.
3. Select the Change Analysis Mode button on the control menu.
4. Select [Body Fluid] mode.Analyzer will automatically perform Autorinse.
5. Select [OK]
6. Place thoroughly mixed vial in tube holder, press Start Switch.
7. If vial barcode is unreadable or barcode reader is inoperable, select the analyzer menu button on the control menu.

a) Select [QC Analysis]

b) From the list of QC files, select the file to be analyzed.Judgment dialog box will open automatically.

c) Place thoroughly mixed vial in tube holder, press Start Switch.

d) When analysis is complete, analysis results are displayed.User should review results and either accept or cancel the run.Accepting the run will transfer the results to the L-J Chart and the Radar Chart for review.

G. Auto-Set Targets

1. 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.

a) Select QC Chart

b) Select [Range] and set cursors so that every data point is included

c) Select [Register]

d) Highlight all parameters and select [Auto Setting]

e) Confirm that the check box for TARGET ONLY is set.Do not select the check box for LIMIT.

f) Select [OK]; the target for each parameter will be calculated and set for the duration of the QC lot.

g) Repeat steps for each new lot of QC being moved into production.

h) Confirm the target set fall within the range of means provided on the XN Check assay sheet provided.

H. Reviewing Quality Control Results

1. QC File screen

a) Allows for review of the latest QC results in Radar Chart format for the QC file that is selected in the list.

b) Any point exceeding the upper or lower limit is marked with a red “X”.

2. QC Chart screen

a) Allows for review of detailed graph data of all QC runs for selected file.

b) Analysis data is plotted cumulatively and displayed in the chart area as a line graph.

c) Any point exceeding the upper or lower limit is marked with a red “X”.

d) User must scroll up and down through the chart to view all parameters for each run.

e) Select [Range] to set a main cursor and a sub-cursor so that data between the two cursors can be manipulated.

(a) Statistics may be analyzed over any selected range.

(b) Targets may be auto-set for the selected range.

(c) To cancel range mode, select [Range] on the toolbar again or exit QC Chart mode.

f) QC charts may be overlaid on top of each other for comparison.

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

(b) Select [Compare Analyzers] to compare QC files for the same material registered to different analyzers (XN-2000 only).

3. Corrective Action for out of range QC Results

a) If quality control results do not meet established criteria, perform the following measures in order until the problem is resolved:

(a) Rerun the control that is outside of 2SD.

(b) Open a new vial of the same level of QC material and rerun the control.

(c) Run third level of control.

(d) Two of three levels for each parameter must be within 2SD of the mean for results to be acceptable.

I. Patient Moving Averages-**Xm** (XbarM)

1. Establishing **Xm**Historical Limit%: The Sysmex XN-2000 calculates Xm based on the last 20 patient samples run through the analyzer (results that trigger multiple flags are not included). This provides a trending analysis for the analyzer that periodic running of quality control may not catch. **Xm** data is kept on three parameters (MCH, MCHC, and MCV).
2. Review Procedure
   a) Review data points covering the preceding 24 hours. If all values are within range (no red X's on Levy-Jennings chart), select and print these data points.
   b) A single instance of a parameter being out of range may be due to a run of patients from a specific area (i.e. ICU) that has abnormal patients. In that case, no further action is needed.
   c) If consecutive moving averages are out of range, run a commercial control and verify that the assay is in range, entering a comment accordingly.
   d) If QC values are out, troubleshoot for problems (refer to maintenance procedures).

Note: Our batch size for **X̄m** is 20 patient samples per batch. Each point on the **X̄m** QC graph represents one batch.Supervisor will review **X̄m** exceptions daily and will perform comprehensive **X̄m** review monthly.

J. Quality Control Management

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

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

a) Hematology QC tech will submit all QC values on-line to the Sysmex *Insight* QC program.

b) A summary of this submission will be printed and given to the supervisor for review.

c) Once the group report is ready, an e-mail is sent from Sysmex to the Hematology supervisor.

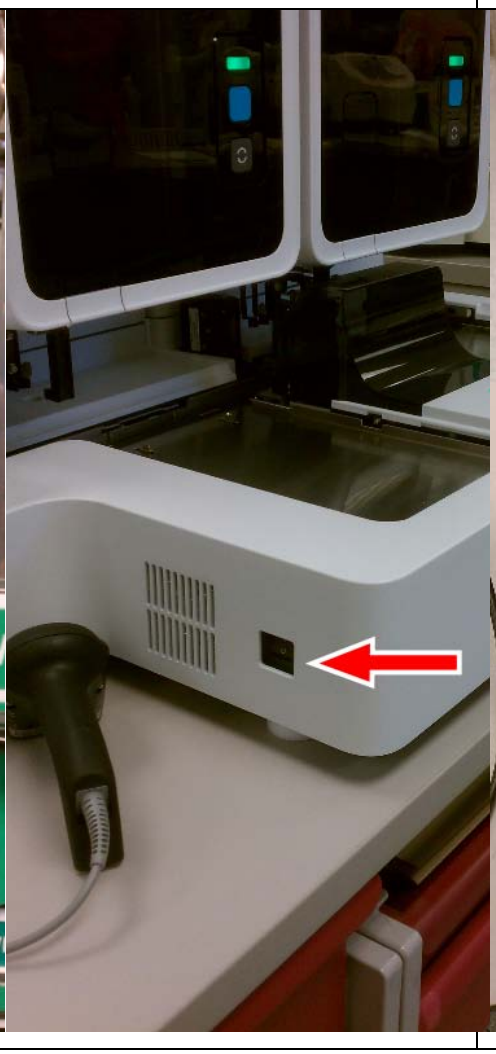
d) Supervisor will download the full peer-group comparison as a .pdf form. The Supervisor will review and digitally sign the report.

VII. OPERATING PROCEDURE

A. Start-Up Procedure

1. Turning ON the entire system

a) Verify that all power switches for each device are in the ON position.

There is one switch on the upper front face of each module behind the upper door. These should never be turned off.	There is a switch on the auto-sampler (left side if facing the analyzer).	Press the power button on the IPU to power ON the entire system.
		

2. When the logon dialog box appears, enter user name and password (User Name is currently: xn. No password is necessary).

3. XN self-checks: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times).

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

4. Analyze Quality Control Material

B. Patient Sample Processing

1. Autosampler analysis)

a) Make sure the analyzer and the sampler are in READY state

b) Check that tube holder has retracted into the analyzer (press Mode Switch  if necessary).

c) Place sample(s) in rack(s) in right sampler pool (analyzer side).

d) Rack(s) will auto-start.

e) Samples will run. Results will be displayed in the IPU.

f) On-Board rules engine will determine repeat or reflex testing

g) Rack will run in reverse to perform repeat or reflex testing.

h) Remove the rack from the left sampler pool when analysis in completed.

i) Make smear if indicated.

2. Manual Analysis

a) Check the status of the analyzer.Confirm the analyzer is ready.

b) If necessary, press the Mode Switch  to eject the tube holder.

c) Select the Change Analysis Mode button on the control menu

d) Select analysis mode

(a) [Whole blood] is selected when whole blood is being analyzed

(b) [Low WBC] Select this to perform low WBC analysis on whole blood

(c) [Pre-Dilution] select when running 1:7 pre-diluted blood.

e) Select [OK]

f) Select Manual Analysis button on the control menu

g) Input sample ID or select [Read ID]

h) Select [OK]

i) Properly mix the specimen and place in the tube holder

j) If running a microtainer, remove the cap using caution to avoid splattering. Press the Start Switch on the analyzer

(a) The tube holder will slide in and the sample will be aspirated

(b) When the analysis is complete, the tube holder slides out

k) Remove the sample, repeat steps for additional samples

l) Review results in IPU to determine whether repeat or reflex testing is required.Rerun sample if required.Make smear if required.

3. Body Fluid Analysis

a) Check the status of the analyzer.Confirm the analyzer is ready.

b) If necessary, press the Mode Switch to eject the tube holder.

c) Select the Change Analysis Mode button on the control menu.

d) Select [Body Fluid]

e) Select [OK]. The analyzer will automatically perform a background check up to three times.

f) Select the Manual Analysis button on the control menu.

g) Input the sample ID or select [Read ID].

h) Select [OK].

i) Properly mix the specimen and place in tube holder.If running a microtainer, remove the cap using caution to avoid splattering.

j) Press the Start Switch on the analyzer.

(a) The tube holder will slide in and the sample will be aspirated.

(b) When the analysis is complete, the tube holder slides out.

k) Remove the sample

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

m) See Body Fluid procedure for details on completing and resulting body fluid specimens.

VIII. Daily and Weekly Cleaning and Shutdown –

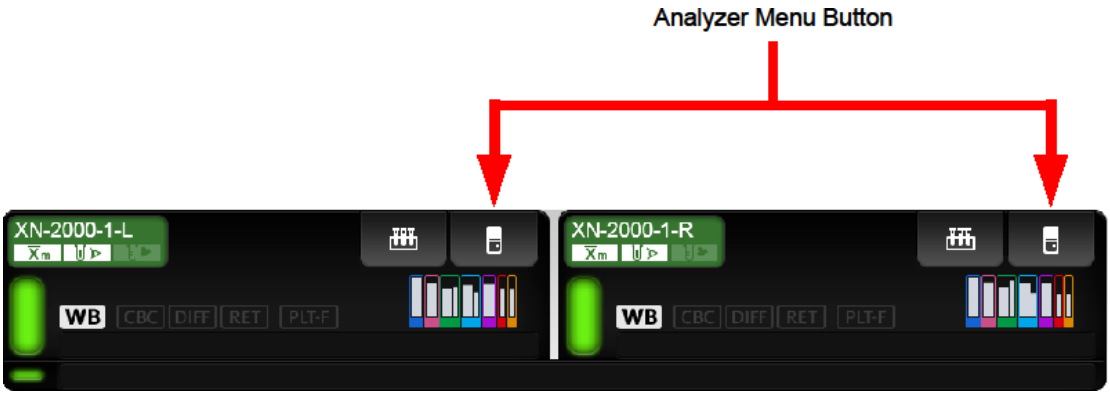
Perform daily on both sides of the analyzer. There are two methods of cleaning. Daily Cleaning will be performed by night shift. It allows the modules to be cleaned and shutdown individually so we limit the downtime of the analyzer. Weekly Cleaning simultaneously cleans and shuts down both analyzers and will done on Sunday by day shift, or if directed by the supervisor or service.

1. **Daily Cleaning**

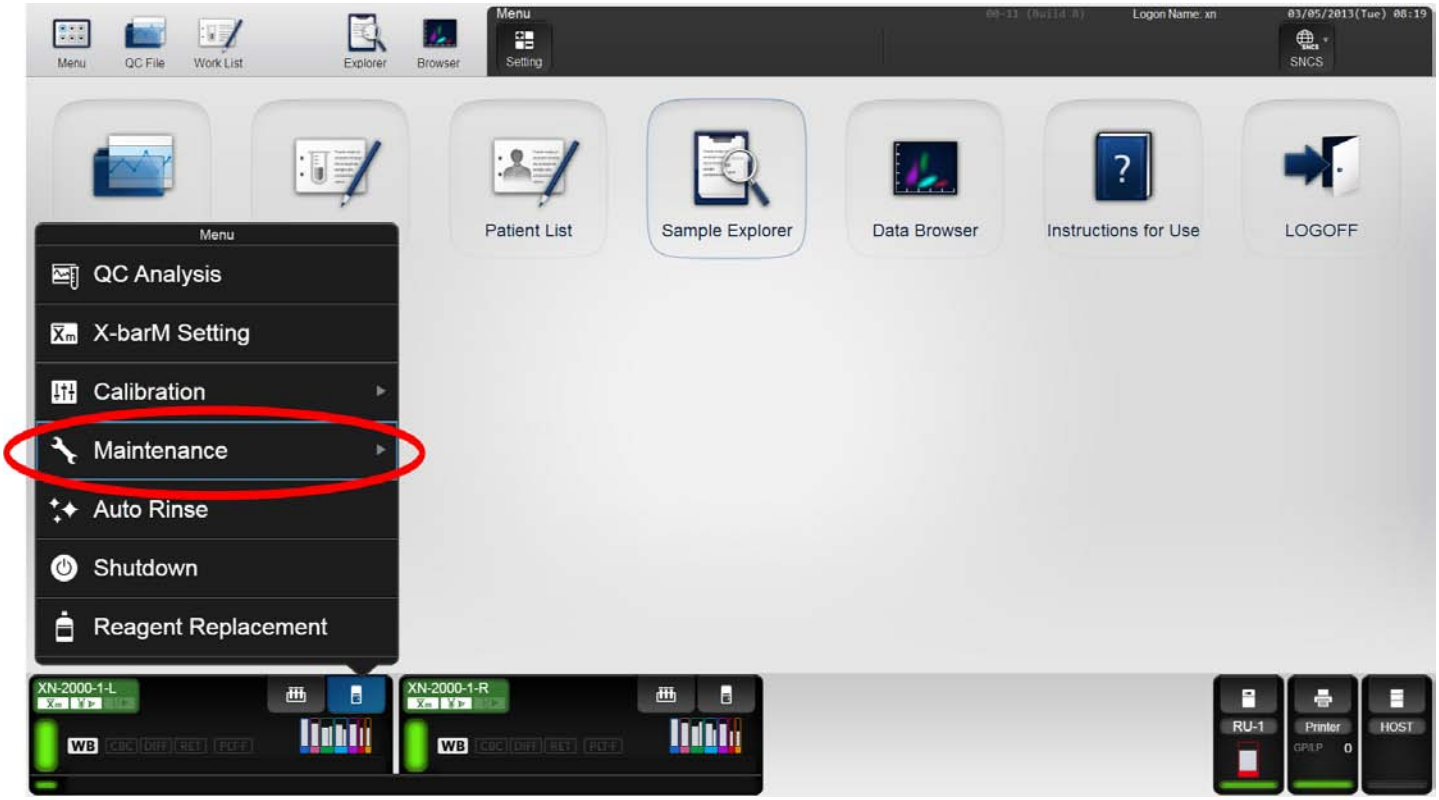
   a) Ensure tube holder is ejected from the analyzer. If it is retracted, press Mode Switch button to eject it.

   b) Place tube of CELLCLEAN AUTO in the tube holder.

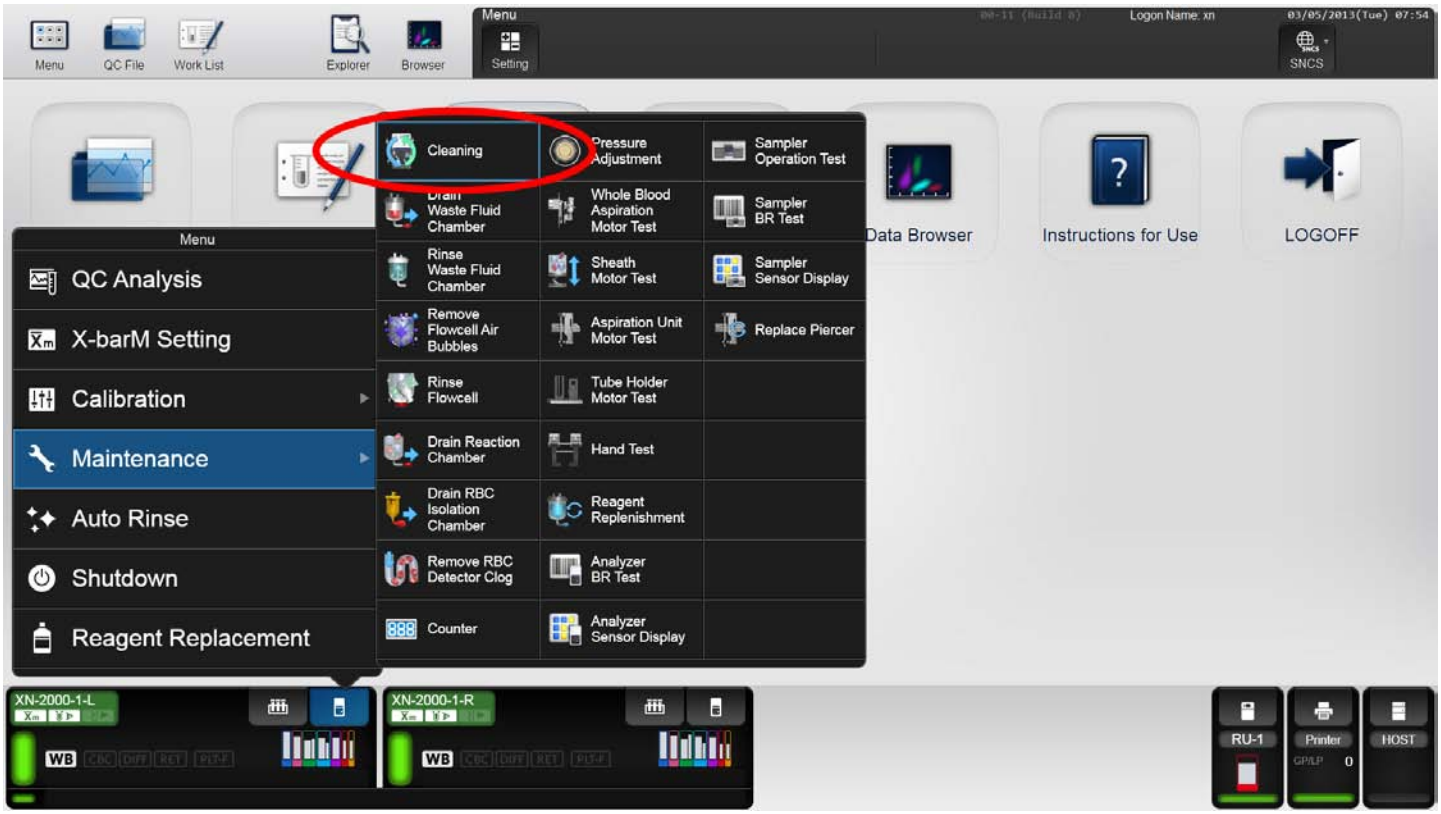
   c) Press the Analyzer Menu button on the IPU touchscreen. A menu will appear.



   d) Select Maintenance.



c) Select cleaning.



e) Press the Analyzer Start Switch . The cleaning cycle takes approximately 20 minutes.

f) When the clean cycle is complete, the analyzer will automatically perform an Autorinse. The IPU will not automatically shut down using this method. Confirm analyzers, sampler unit are at ready.

g) Run all 3 levels of control after completion of daily cleaning.

2. Weekly Cleaning (performed on Sunday, dayshift) Refer to the XN-2000 Instructions for Use for detailed illustrated procedures.

a) Confirm tube holders are retracted into the analyzers.

b) Obtain empty rack.

c) Place 2 tubes of CELLCLEAN AUTO in rack, positions 9 and 10. This rack will shut down the XN's.IPU will automatically shut off at the conclusion.

d) Place racks on sampler unit, sampler unit will auto-start.

e) When completed, press the IPU power button to re-start analyzer.

f) Run all 3 levels of control after completion of weekly cleaning.

B. Maintenance

Maintenance performed on the XN will be automatically tracked in the maintenance history (accessible from Admin login). Also – log on XN-2000 Monthly Maintenance form.

There is no scheduled monthly or quarterly maintenance.

Refer to XN *Instructions for Use* for ‘as needed’ maintenance.

IX. Calculations

A. If making a dilution of a patient specimen and running in Whole Blood Mode, multiply appropriate parameters by the dilution factor. If running in [Pre-Dilution] mode, the analyzer will multiply by the correction factor (The analyzer will only perform calculations based on a 1:7 dilution. If using a different dilution, run in Whole Blood mode and perform calculations by hand).

B. If correcting the HGB or HCT due to interfering substances recalculate and correct the affected indices:

$$MCHC = \frac{HGB}{HCT} X\ 100$$

$$MCH = \frac{HGB}{RBC}\ X\ 10$$

$$MCV = \frac{HCT}{RBC} X\ 10$$

C. If a sodium citrate tube is used for EDTA induced platelet clumping, multiply the citrate platelet count and WBC count by 1.11 to correct for anticoagulant dilution. Use the citrate MPV (to avoid sizing inaccuracies caused by clumps) but do NOT multiply by 1.11.

X. REPORTING RESULTS

1. The XN-2000 will automatically repeat a specimen for the following reasons:
   a) Any instrument function errors.
   b) Specimen flags that indicate a repeat needed for additional tests either due to low counts (WBC) or to perform an optical platelet.

2. Specimens with flags will automatically print out with a numeric code indicated the error (see chart next page for active flags), and a brief action comment on the appropriate follow-up. These specimens are referred to as 'Positive'.
   a) These printed specimens have follow up issues that need to be addressed.
   b) If an ellipsis (**. . .**) appears under a flag, this indicates that multiple additional flags are present. To view, double click on the specimen in the Explorer screen on the IPU. The highest priority flag will always be printed on the printout.
   c) The flags will not cross to MCare. When resulting, make sure you have all printouts from the XN-2000 to assist.

3. Specimens that do not have any flags are considered 'Negative' and will not print.

4. Specimens with a manual diff ordered and are 'Negative' will not print – you will have to request a printout by:
   a) Highlight the specimen in Explorer.
   b) Select Output from toolbar and select GP.

5. Delta flag will not appear on the XN-2000 printout. They will come up in MCare. Please follow the chart below for delta checks that require follow-up action.

   a) Evaluate instrument flags first.

   b) Take into consideration all CBC results, previous trends in patient CBC results and clinical information to determine significance of delta values.

   c) Obtain redraw is result do not match clinical information.

Delta Flags (in MCare)

Test	**SR**	**HGM**
WBC (results within normal range)		**X**
WBC (results > than previous and > 20,000	**X**	
WBC and NEUT% increase	**X**	
PLT < 100, PT had surgical procedure or HGB < previous.		**X**
PLT < 100, all previous PLT counts > 100, no clinical reason for decrease	**REDRAW!**	
Neut% (>previous)	**X**	
Neut% (<previous)		**X**
RBC or HGB		**X**
MCV > previous, previous MCV < 70 and pt received PRBCs	**X**	
MCV > previous, pt received no blood products	**REDRAW!**	
MCV > previous, previous > 85, patient on IV with D5.	**REDRAW!**	

All flags print with just the flag number and follow up action.

Tests requiring automatic repeat testing:

XN-2000 flag	Test	Reason	Follow up action (if flag repeats)
#7 LWBC Reflex	WBC	And WBC < 1.0	MD 1st spec, HGM 2nd or later.
#27 WBC Suspect	WBC	Problem with WBC count	N/A – review slide to review WBCs
#37 RBC Fragments	PLT-F	RBC frags interfere w/ plt.	SR (to scan for fragments.)
#42 Ret Abn Scat	RET	Problem with scattergram	N/A – Dilute 1:7 w/ DCL and re-calc.
#75 PLT Clumps?	PLT-F	Possible platelet clumps	N/A, review slide for clumps
#77 Platelet Critical	PLT-F	Platelet count < 50	Crit, MD/PR -1st, HGM 2nd or later
#78 Thrombocytopenia 1	PLT-F	Platelet count < 80	MD/PR on 1st, HGM 2nd or later.
# 81 PLT Abn Distribution	PLT-F	Problem with impedance plt.	Will not appear with PLT-F.

Linearity Flag requiring dilution before resulting:

XN-2000 flag	Test	Reason	Follow up action
#13 WBC Linearity	WBC	WBC > 500	N/A – Dilute 1:7 w/ DCL and re-calc.
#15 NRBC Linearity	CBC	NRBC> 600	N/A – Dilute 1:7 w/ DCL and re-calc.
#41 Retic Linearity	RET	Retic > 19.6%	N/A – Dilute 1:7 w/ DCL and re-calc.
#46 HGB Linearity	CBC	HGB > 27	N/A – Dilute 1:7 w/ DCL and re-calc.
#50 HCT Linearity	CBC	HCT > 74.9	N/A – Dilute 1:7 w/ DCL and re-calc.
#80 PLT Linearity	PLT	PLT > 5,054	N/A – Dilute 1:7 w/ DCL and re-calc.

Suspect population/morphology flags ***If no previous slides made, handle flags as 1st spec of admit.**

XN-2000 flag	Reason	1st spec of admit.			2nd or greater*		
		PR	MD	SR	MD	SR	HGM
#1 WBC ABN SCT	Suspect WBC/auto-diff.		X			X	
#2 Left Shift	Possible left shift			X			X
#3 Atyp Lymph?	Possible atypical lymphs		X				X
#4 Blast/Abn Ly?	Possible Blasts, immature/atyp. lymphs.		X			X	
#5 ABN Lympho?	Possible abnormal lymphocytes.		X			X	
#6 Blasts?	Possible Blasts present		X			X	
#8 WBC Crit 1	Critical value WBC (< 1.5 or > 100)	X					X
#12 WBC Path Review	WBC < 3.0 or > 35.0	X					X
#16 Leukocytosis	WBC > 20			X			X
#17 Leukopenia	WBC < 3.0	X					X
#18 Neutrophilia	Neut. >90%	X					X
#21 Lymphocytosis 1	Lymph > 80%	X					X
#22 Lymphocytosis 2	Lymph > 90%, < 12 years old	X					X
#23 Monocytosis	Mono > 20%	X					X

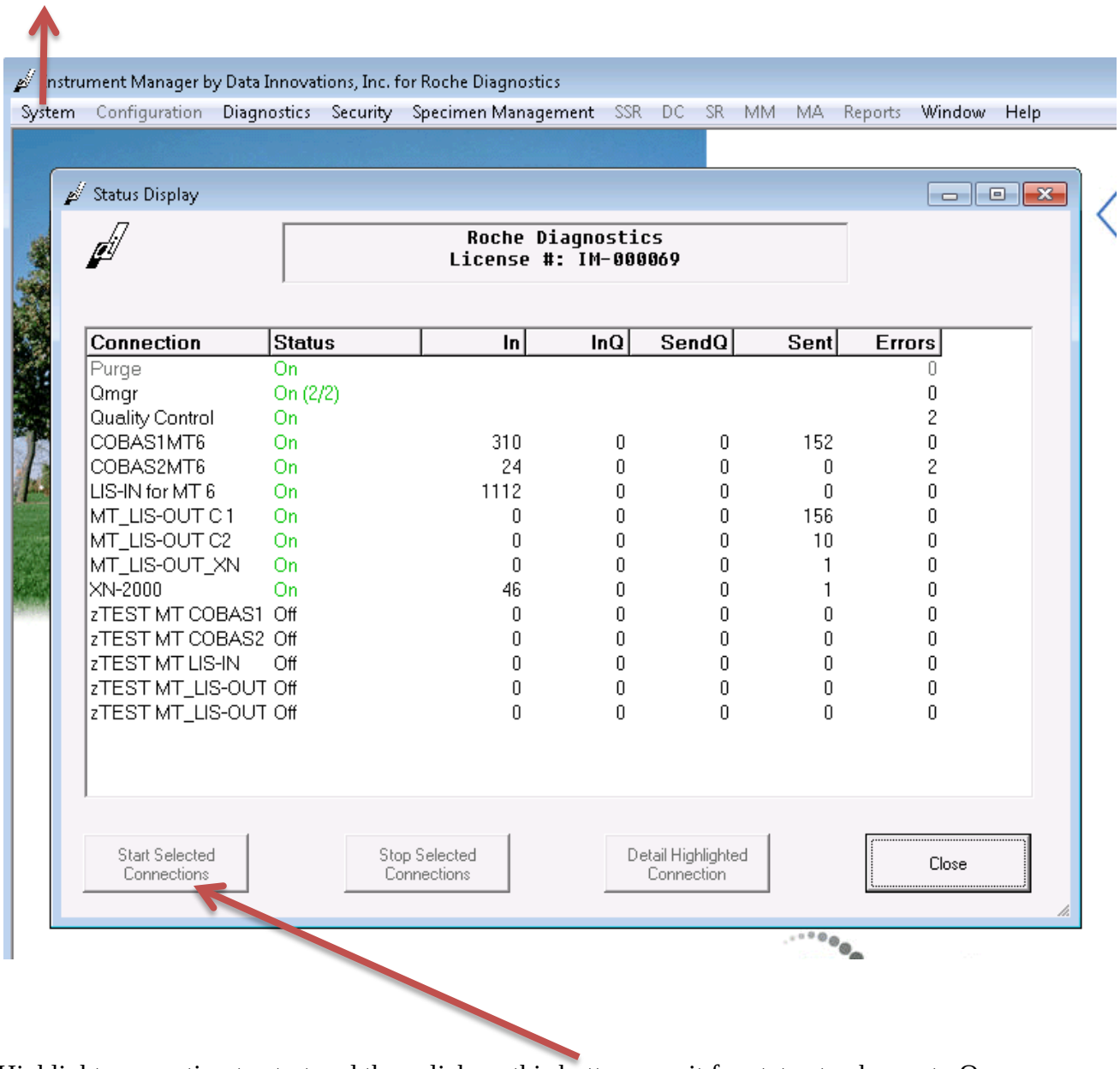
XN-2000 flag	Reason	1st spec of admit.			2nd or greater*		
		PR	MD	SR	MD	SR	HGM
#24 Eosinophilia	Eos > 20%	**X**					**X**
#25 Basophilia	Baso > 5%	**X**					**X**
#26 High IG%	IG > 5%	**X**				**X**	
#31 Dimorphic RBCs	Dimorphic RBC population			**X**			**X**
#32 RBC Abn Dist	Abnormal RBC distribution			**X**			**X**
#33 RBC Agglutination	Possible RBC Agglutination			**X**		**X**	
#34 RBC Iron Def	Possible iron deficiency			**X**			**X**
#35 High MCHC	Turbidity/HGB interference, MCHC > 37.5			**X**			**X**
#36 HGB Defect	Possible abnormal RBC morphology			**X**			**X**
#38 RBC Critical 1	Critical Value RBC (> 6.0 F/ >6.60 M)	**X**					**X**
#43 HGB Critical 1	HGB Critical value, HGB > 24.0, < 6 D	**X**					**X**
#44 HGB Critical 2	HGB critical < 7.0 or > 20.0, > 6d	**X**					**X**
#54 MVC Path Review	MCV < 70.0 or > 105.0	**X**					**X**
#55 High RDW-CV	RDW > 25.00	**X**					**X**
#76 PLT ABN Scat	Abnormal PLT scattergram.			**X**		**X**	
#79 Thrombocytosis	PLT > 800	**X**					**X**

DI interface:

The Xn-2000 is interfaced to MCare via the DI (data innovations) server. If there is an issue with the interface (result not crossing to MCare, or an error message pops up on the XN-2000, please check that the interface with DI is running. You can do this at the PC on the backup diff bench:

1. Click on the Shortcut to instrument manager.
2. User name is TECH, password, TECH.
3. Select System from the toolbar (upper left hand side).
4. Select Status form the drop down menu. (see next page for picture)
5. Make sure Qmgr, LIS-IN and XN-2000 are on.
6. If either are off, highlight that line and click on Start Selected Connection to reset the interfaces.

Click on System and select Status to pull up Status display.



Highlight connection to start and then click on this button – wait for status to change to On.

XI. PROCEDURE NOTES

A. Megakaryocytes:when megakaryocytes are present, perform a WBC and PLT estimate.

B. Pre-Dilution Mode

1. Use when insufficient patient sample is available for aspiration in the open mode (<130µL) or a sample has a parameter above the linearity limits of the analyzer.
2. Because of the dilution factor reduces the reliability of the differential, only a CBC or CBC+RETIC discrete panels can be selected.

C. Delta values should be reviewed for their significance:

All delta values should be resulted with a RR ("Results Reviewed") canned comment.

If result questionable or do not match patient's condition, have specimen re-drawn to verify. Do not verify initial result; cancel the specimen not reported.

1. WBC:
   a) ↑delta – infection, post-op, post-transfusion, etc.
   b) ↓ delta – antibiotic therapy, chemotherapy, etc.
2. HGB:
   a) ↑ delta – transfusion, removal of IV, EPO administered, etc.
   b) ↓delta – active bleeding, start of IV therapy, etc.
3. MCV: ↑ delta – if the original MCV was very low (<70) and patient has been transfused, then you can result. For ***all*** other instances a redraw should be done to confirm results. If redraw confirms result, investigate previous results and consult with supervisor.
4. PLT:
   a) ↑ delta – platelet transfusion, recovery from surgery, etc.
   b) ↓ delta – active bleeding, post surgical, chemotherapy, etc.
5. NEUT%:
   a) ↑delta – infection, increase in immature cells, etc.
   b) ↓delta–antibiotic therapy, chemotherapy, etc.
6. Make slides as necessary and proceed per "Manual Differential/Smear Review procedure."

XII. LIMITATIONS OF PROCEDURE

A. XN-Series MANUFACTURER STATED LINEARITY

Parameter	Range	Units
WBC	0-440.0	$x10^3/\mu L$
RBC	0-8.60	$x10^6/\mu L$
HGB	0-26.0	g/dL
HCT	0-75.0	%
PLT, PLT-F	0-5000	$x10^3/\mu L$
RET%	0-30	%
NRBC%	0-600	/100 WBC
BF- WBC	0.003 – 35.6	$x10^3/\mu L$
BF-RBC	0.002 - 4.10	$x10^6/\mu L$

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.

1. Parameters that exceed these limits are flagged with @ beside the result. The sample must be diluted 1:7 with DCL and run as pre-dilute in open mode. Result from pre-dilute mode will be calculated correctly for the 1:7 dilution.

2. Note the use of dilution for linearity on the patient report.

XIII. KNOWN INTERFERING SUBSTANCES

A. Specimens must be free of clots and fibrin strands.

B. 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.

C. Red cell fragments, microcytic RBC's or white cell cytoplasmic fragments may interfere with automated platelet counts. A fluorescent platelet count may be performed to avoid this interference.

D. Cold agglutinins produce spurious macrocytosis, elevated MCH and/or MCHC, or falsely decreased RBC counts and HCT's. Rare warm agglutinins produce the same spurious results as a cold agglutinin.

E. Extremely elevated WBC's may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values.

F. Severely hemolyzed samples (in vitro) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.

G. 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 collecting blood into sodium citrate anticoagulant and reanalyzing, 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.

H. Severe Lipemia falsely elevates HGB & MCHC. Perform a plasma replacement or plasma blank procedure.

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

J. Rocking specimen excessively may affect the WBC differential.

XIV. INSTRUMENT EVENTS – PROBLEM SPECIMEN CHART		
Parameter Marks	**Description**	**Action**
@	Data outside of Linearity Limits	Perform Cellpack dilution. If using 1:7, you may use Pre-Dilution mode. Indicate on report that dilution was used.
***** (WBC/Diff parameter)	Data is Doubtful (IP or Suspect Message)	Perform Smear Review
***** (PLT)	Data is Doubtful (IP or Suspect Message)	Rerun in RET mode for optical platelets if flags persists - review slide for large platelets, clumps, etc.
***** (MPV)	Data is Doubtful (IP or Suspect Message)	RNR MPV
+, -	Data exceeding Reference Interval (high or low)	No action
- - - -	Analysis can't be performed	Repeat analysis on secondary analyzer. If not resolved, perform manual method (differential, manual retic, etc.)
+ + + +	Data exceeds display range	1) Check sample mode: undiluted sample may have been run in capillary mode 3) Check for aspiration error 2) Perform dilution
" " (Blank)	No order for test	No action (check to see if specimen has been collection verified, or is a CBC test ordered)

Parameter Marks	Description	Action
& (WBC)	Correction for NRBC	No action (See * (NRBC?) above)
& (LYMPH)	Correction for NRBC	No action (See * (NRBC?) above)
& (NEUT)	6-part Diff used (this is the default analyzer setup)	No action
& (PLT)	PLT-O used	If a platelet flag persists, review slide for clumps, large platelets, etc.
SLIDE EVENTS		
SEEN ON SLIDE	**LIKELY PROBLEM**	**SOLUTION**
Platelet clumps present on slide.	1. Clumps in specimens due to draw. 2. Patient's platelets clump in EDTA.	Redraw specimen in both EDTA and NaCit. See Section I of Problem Specimen procedure.
Giant platelets seen on slide.	Giant platelets may have interfered with RBC and WBC results.	Determine if giant platelets are interfering with other results. See Section I of Problem Specimen procedure.
A. Smudge cells seen on slide	Artificially decreased WBC, incorrect auto diff % and #, increase PLTS.	Evaluate analyzer results for accuracy.
WBC count appears lower then analyzer result.	Abnormal proteins present.	Dilute with Cellpack and rerun to verify WBC results.

XV. Reference Ranges

Parameter	Adult Male	Adult Female	Pediatric	Neonatal	Units	Alert Value
WBC	4.6-10.2	4.6-10.2	4.0-15.0	4.0-15.0	$x10^3$	<1.50
RBC	4.11-5.71	3.76–4.80	3.80-6.00	3.90-6.80	$x10^6$	
HGB	13.0-17.0	11.0-15.0	11.0-18.0	13.0-23.0	g/dL	< 7.0 ≥ 20g/dL
(newborn)						> 24 g/dL
HCT	38.2-48.5	33.0-43.0	37.0-54.0	41.0-61.0	%	
MCV	80.0-97.0	80.0-97.0	78.0-91.0	89.0-101.0	fL	
MCH	27.0-31.2	27.0-31.2	25.0-33.0	34.0-38.0	pg	
MCHC	31.8-35.4	31.8-35.4	33.0-35.0	34.0-36.0	g/dL	
RDW	11.6-14.8	11.6-14.8	11.6-14.8	11.6-14.8	%	
PLT	124-400	124-400	142-424	142-424	$x10^3$	<50
MPV	7.4-10.4	7.4-10.4	7.4-10.4	7.4-10.0	μm^3	
% Neutrophils	37.0-85.0	37.0-85.0	24.0-82.0	24.0-82.0	%	
% Lymphocytes	5.0-45.0	5.0-45.0	10.0-55.0	10.0-55.0	%	
% Monocytes	3.0-15.0	3.0-15.0	0.0-8.0	0.0-8.0	%	
% Eosinophils	0.0-7.0	0.0-7.0	0.0-8.0	0.0-8.0	%	
% Basophils	0.0-2.0	0.0-2.0	0.0-2.0	0.0-2.0	%	
% IG	0.0-3.0	0.0-3.0	0.0-3.0	0.0-3.0	%	
Neutrophils #	2.0-8.0	2.0-8.0	0.0-10.0	0.0-10.0	$x10^3$	
Lymphocytes #	0.6-3.4	0.6-3.4	0.0-7.0	0.0-7.0	$x10^3$	
Monocytes #	0.0-1.2	0.0-1.2	0.0-1.2	0.0-1.5	$x10^3$	
Eosinophils #	0.0-0.7	0.0-0.7	0.0-0.8	0.0-0.8	$x10^3$	
Basophils #	0.0-0.5	0.0-0.5	0.0-0.4	0.0-0.4	$x10^3$	
IG #	0.0-0.4	0.0-0.4	0.0-0.4	0.0-0.4	$x10^3$	
%Retic	0.5-1.5	0.5-1.5	2.5-6.5	2.5-6.5	%	

These normal ranges verified with installation of Sysmex XN-2000 analyzer – 1/14/08.

XVI. REFERENCES

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PROCEDURE AND FORM CHANGE CONTROL

Title: Sysmex XN-2000 procedure											
Written	Date	By	Validated By	Date	Path Review	Date	Review By	Date	Effective Date	By	Reason for Revision
	6/2013	BEM	EWE	11/2013	ESB	11/21/13	KSM	12/3/13	12/5/13	EWE	
Revised											

Out of use:

Date: _____ By: _____ Reason: _____