

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

Clinical Significance:

The CBC and differential provides in-depth quantitative analysis of the three cellular/particulate components of peripheral blood. 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.

I. PRINCIPLE

The analytical module (XN-10) is a quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 31 whole blood diagnostic parameters.

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), and nucleated red blood cells (NRBC) 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

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.

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A. Required specimen

1. Whole blood should be collected in EDTA-2K anticoagulant.

B. Specimen volumes required

1. Optimal draw is a 12 x 75 mm tube filled to capacity
2. A minimum of 1 mL of whole blood is required for sampler analysis.
3. Manual analysis whole blood mode
 - a. Closed tube – 1 mL
 - b. Open tube – 300 µL
 - c. Open microtube – 160 µL

C. Unacceptable specimens including those 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. Do not use samples collected in sodium citrate for platelet counts.
3. Grossly hemolyzed samples
4. Samples drawn above an IV line

D. Characteristics that may affect test results:

1. Lipemia
2. Icterus
3. Cold agglutinins

E. Stored Specimen Stability

1. Stored at 4-8°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, which may be minimized by refrigeration.
3. Allow refrigerated samples to come to room temperature and mix well before analysis.

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

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III. SUPPLIES & 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™

B. Sysmex Reagents

1. Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-Series modules.
2. All reagents are used at room temperature and are to be used within the Manufacturer's expiration date on each container.
3. Record date received and date opened on container.
4. All reagents are azide free and are intended for *in vitro* diagnostic use only. **Do not** ingest.

<u>XN REAGENTS</u>	<u>OPEN EXPIRATION</u>
CELLPACK DCL	60 Days
CELLPACK DST	60 Days
CELLPACK DFL	60 Days
SULFOLYSER	90 Days (5.0L)
Lysercell WNR	60 Days
Fluorocell WNR	90 Days
Lysercell WDF	90 Days
Fluorocell WDF	90 Days
Fluorocell RET	90 Days

C. 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
 - a. Unopened, it is stable until expiration date printed on the container.
 - b. Opened, it is stable for 60 Days.

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CELLPACK DCL Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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 DCL does not have ingredients with those characteristics.**

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

CELLPACK DST Storage

- a. Store at 2°-35°C away from direct sunlight.
- b. Do not use the reagent if it is suspected to have frozen.
- 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

- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 60 Days.

CELLPACK DST Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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 DFL (DFL):** Whole blood diluent 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

- a. Store at 2°-35°C away from direct sunlight.
- b. Do not use the reagent if it is suspected to have frozen.
- c. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

CELLPACK DFL Stability

- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 60 Days.

CELLPACK DFL Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS documentation of ingredients which have

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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.**

D. Lysing 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°) 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

- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 90 Days (5L).

SULFOLYSER Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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. **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

- a. Store at 2°-35°C away from direct sunlight.
- b. Allow the container to equilibrate to environmental temperature (15-30°) 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

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- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 60 Days.

Lysercell WNR Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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, 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°) 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

- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 90 Days.

Lysercell WDF Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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.**

E. 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.

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Fluorocell WNR Stability

- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 90 Days.

Fluorocell WNR Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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 SDS.

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

Fluorocell 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 WDF Stability

- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 90 Days.

Fluorocell WDF Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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 SDS.

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

- a. Unopened, it is stable until expiration date printed on the container.
- b. Opened, it is stable for 90 Days.

Fluorocell RET Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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

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exceed permissible exposure limit/threshold limit values or have been identified as carcinogens.

Refer to the SDS.

F. Cleaning Agent

1. **CELLCLEAN AUTO**: Detergent for fully automated hematology analyzer. To be used as a strong alkaline detergent 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

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

CELLCLEAN AUTO Hazard Risk

- ❖ The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires SDS 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 SDS, CELLCLEAN AUTO is corrosive and may cause burns to skin.

G. Commercial Control Material for XN analyzers

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 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
 1. Consists of human red and white blood cells with a platelet component suspended in fluid medium.
 2. Each vial contains 3 mL of control material.

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- d. Storage
 - 1. Store vials at 2-8°C
 - 2. Do not freeze or expose to excessive heat.
- e. Stability
 - 1. Unopened and properly stored, XN CHECK is stable until the expiration date printed on the unopened vial.
 - 2. Open vial stability is 7 days when promptly refrigerated after each use.
 - 3. Record the date on each vial upon opening or cap piercing.
 - 4. Heating 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.
 - 5. If deterioration is suspected, call the Sysmex Technical Assistance Center.
1-888-879-7639 (1-888-8SYSMEX).

H. Calibrators

WARNING: Risk of Infection Always wear PPE when using control blood products. Also, wash your hands after completing the process. The basic blood used in the control blood has tested negative for HBs antigen, HCV/HIV-1/HIV-2 antibodies, and serologic tests for syphilis. However, there are no tests that can completely rule out any infections. In addition, it has not been tested for other viruses. Therefore, handle it with the same level of care you would use when handling other blood samples that may be infectious.

- 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
 - a. Unopened and properly stored, XN CAL is stable until the expiration date printed on the unopened vial.
 - b. Open vial stability is 4 hours.

I. XN Reagent Replacement

Document all reagent changes on the appropriate log.

- 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].
 - 1. Remaining Reagent Volume indicator appears.

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3. Replacing a new diluent / hemolytic agent

- a. Display the [Reagent Replacement] dialog box.
- b. Remove the cap from the new reagent container.
 1. Confirm the reagent has not expired.
- c. Input the reagent code (barcode).
 1. Place the cursor in the reagent code field.
 2. Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.
 3. Select [OK].
- d. Remove the cap from the old reagent container.
- e. Pull out the dispensing set straight up.
- f. Insert the dispensing set straight up into the new reagent container.
- g. Close the cap.
- h. Select [Execute].
 1. Reagent replacement starts. When complete, the dialog box closes automatically.

4. Replacing CELLPACK DST with an RU-20

- a. Display the RU-20 Maintenance menu.
- b. Select [Replace Reagent].
- c. Remove the cap from the new reagent container.
 1. Confirm that reagent has not expired.
- d. Input the reagent code (barcode).
 1. Place the cursor in the reagent code field.
 2. Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.
 3. Select [OK].
- e. Remove the cap from the old reagent container.
- f. Pull out the dispensing set straight up.
- g. Insert the dispensing set straight into the new reagent container.
- h. Close the cap
- i. Select [Execute].
 1. Reagent replacement starts. When complete, the dialog box closes automatically.

5. Replacing Dye

- a. Display the [Reagent Replacement] dialog box.
- b. Prepare the new reagent cartridge.
 1. Confirm the reagent has not expired.
- c. Open the top front cover.
- d. Pull up the cover from the reagent that is to be replaced.
 1. When the dye solution cover is pulled up, a Help dialog box appears in the IPU screen.
- e. Remove the old reagent cartridge from its holder.
- f. Install the new reagent cartridge into the holder.

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1. 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.
2. If the wrong reagent is installed, the analyzer beeps repeatedly and the Help dialog box appears in the IPU screen.
- g. 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.
- h. Close the top front cover.
 1. Reagent replacement starts.
 2. When complete, the reagent replacement window closes automatically.

IV. CALIBRATION and PRECISION

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

The laboratory 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 calibrator: WBC, RBC, HGB, HCT, PLT, 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.

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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:
 - a. Be a healthy person who is not taking any medication.
 - b. Have morphologically and numerically normal CBC.
 - c. Be drawn in potassium EDTA anticoagulant tube using proper collection technique.
 - d. Have a minimum of 2.5 mL of sample.
4. On the main unit, check the Status indicator LED. Confirm the LED is green indicating the analyzer is Ready.
5. If the tube holder has not ejected out, press the mode switch.
6. Select the Change Analysis Mode button on the control menu and select Whole Blood.
7. Select [OK] to close the dialog box.
8. Select the Analyzer menu button on the control menu.
9. Select [Calibration] – [Precision Check].
10. Mix the vial containing the sample – 10 end-over-end inversions confirming cell button is dispersed.
11. Place the vial in the sample tube holder.
12. 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.
13. 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.
 - b. 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.
14. When all analysis results satisfy the conditions, select [OK] in the dialog box.
15. Select [Yes] to record passing precision results in the precision check history.

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 out, 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 package insert.

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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 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.
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. $80\% \leq \text{New Rate} \leq 120\%$
 - b. $\text{New Rate} - \text{Current Rate} \leq \pm 5$
 - c. $\text{Range Value} \leq \text{Max Range}$
 - d. $\text{Acceptable Limit} \leq \text{Delta Percent} \leq \text{Service Limit}$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.
15. Select [OK] to update the compensation rates. The calibration process is logged in the calibrator calibration history.

V. QUALITY CONTROL

Quality control is performed in order to monitor an analyzer's performance over time. XN CHECK is the material used to monitor the performance of the XN analyzer. Quality control runs are performed each day of instrument use. It should be noted that for troubleshooting purposes, additional control runs may be necessary.

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A. XN CHECK Commercial Controls

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.

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. Frequency of Control use and review

XN CHECK control levels: L1, L2, and L3 will be performed each day of use prior to patient testing. Evaluate all control results before patient testing.

The supervisor or delegated technologist reviews QC charts monthly.

C. 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 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.

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9. Perform parallel studies between production lot and new lot prior to production lot expiration.
 - a. Perform a minimum of 10 data points, a minimum of twice (2) a day for five (5) days prior to expiration of current lot.

D. XN CHECK QC Analysis

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

E. Auto-set Targets

1. Parallel test new controls by analyzing each level, L1, L2, and L3, a minimum of twice a day for 5 days prior to expiration of current 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 targets set fall within the range of means provided on the XN Check assay sheet provided.

F. 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.
 1. Statistics may be analyzed over any selected range.
 2. Targets may be auto-set for the selected range.

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3. 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.
 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.
3. Troubleshooting Quality Control
 - a. Results exceeding the upper or lower limit of acceptability.
 1. Make sure vial is at room temperature, 15 minutes before use.
 2. Check open date for 7-day stability
 3. Verify the cell button in the bottom of the vial is completely suspended. Mix vial by gentle end-to-end inversion until button is completely suspended.
 4. Rerun QC
 - b. 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).
 - c. Out of range commercial control products and X-barM.
 1. Document corrective action in the QC log on the analyzer.
 2. Check the expiration dates of your associated reagents. Note the lot numbers and expiration dates.
 3. If this problem occurred with a new lot of control material, note the previous lot number of controls and the values obtained. If you are using more than one level of control, inspect your data to ascertain if the problem exists at all levels.
 4. If this problem occurred with a new lot of control material, note the previous lot number of controls and the values obtained. If you are using more than one level of control, inspect your data to ascertain if the problem exists at all levels.
 5. Check the analyzer for obvious malfunctions such as reagent leaks.
 6. If the problem remains, perform the cleancell auto.
 7. If the problem still remains, select a normal patient specimen that is less than 4 hours old. Analyze this specimen 12 times. Discard the first 2 determinations. Inspect the results for trending and unusual scatter. If the data appears to be within a variation that you normally observe, calculate the CV for the parameter that is in question. Compare this CV to the published instrument performance specification in the Product Reference Sheet. If your value exceeds these limits, call Sysmex.

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

G. 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.

H. Recording and Storage of QC Data

1. Printing and saving QC Data
 - a. Select QC Files Icon and highlight file to output.
 - b. Select QC Chart Icon.
 - c. Set Range of points to output by clicking [Range] and capturing the points with the cursors.
 - d. Select [output] to print the selected chart to either GP or LP.
 - e. Select [file] to save the data to removable media.
2. QC, Data Points, L-J Charts are downloaded to the LIS and printed to an electronic document monthly.
3. Retain QC and X-barM data for a minimum of 2 years

I. *Insight*[™] Quality Assurance Program (QAP)

The ***Insight*** account number is 23973

The XN serial # is XN-10 27970

Laboratory Supervisor or delegated technologist is responsible for saving the data to a USB memory device and submitting by due date in lieu of an SNCS connection.

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

Laboratory Supervisor or delegated technologist is responsible for reviewing results and **Insight** reports.

1. Each lot has two 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 and submit the data. Contact the **Insight** team with questions at: 888-879-7639 (888-8SYSMEX).

J. X-barM Moving Patient Averages

Moving averages are used to verify instrument performance over a period of time. The moving average can help identify a analytical error before this can be determined by running commercial quality control The moving averages are set up to capture MCV, MCH, MCHC, CHCM, NEUTx, NEUTy MNx, and MNy. This will monitor the RBC indices’ and the placement of the WBC’s in the cytogram. The number of patient results included in each calculation is 20. The formula to calculate these parameters is Bull’s Algorithm. All flagged results are excluded. The MVC, MCH, and MCHC can flow across the interface and be evaluated by each technologist like any other control result. The WBC flags can only be monitored on the analyzer control screen.

1. Establishing X-barM Limit%
 - a. Data will be collected over multiple reagent lots and over at least one month including all types of patient samples normally encountered.
 - b. Moving Average: Suggested action if a change in RBC indices is observed in two back-to-back observations

Moving Average: Suggested Action			
MCV	MCH	MCHC	Suggested parameters to investigate
change	same	change	Hct or MPV
same	change	change	Hgb
change	change	same	RBC
change	change	change	RBC, Hgb, Hct, or MPV

2. Batch size and review frequency
 - a. Complete this section with your lab’s batch size and chart review frequency. X-barM can be monitored in lieu of a retained patient

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

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 20 patient samples per batch. Each point on the X-barM graph represents one batch. Supervisor will review X-barM charts every 30 days.

3. Activating / deactivating X-barM Control
 - a. Select the analyzer menu button on the control menu.
 - b. Select X-barM Setting.
 - c. Click [Execute] to perform X-barM Control, Click [Cancel] to deactivate.
 - d. Click [OK].

K. Retained Patient Controls

Retained patient controls are performed in conjunction with X-barM moving patient averages to detect random error and to verify instrument performance throughout the day.

1. Select two normal samples. The parameters that will be monitored are: WBC, RBC, Hgb, MCV and Plt.
2. Retained patient controls (or Precision Controls) will have a defined range of CBC values. Please see the precision control log sheet for these values.
3. Two patient controls are used throughout the day.
4. Record results on the Precision Control log sheets and verify that they are within tolerance limits.
5. If results are not within the tolerance limits, a different precision control should be analyzed. If the problem persists, run XN Controls. If there is not an instrument problem, discard this precision control, and start a new one. Patient results are not to be reported until the controls are within tolerance limits.
6. If a problem does exist, consult the Troubleshooting Section in the on-line Operator’s guide on the XN.

Tolerance Limits	
WBC	± 0.6 x 1000/cumm
RBC	± 0.2 x 1000/cumm
HGB	± 0.4 gm/dl
MCV	± 5.0 fl
PLT	± 30 x 1000/cumm

Note: Precision Controls can be tested in either open or closed tube mode

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

VI. OPERATING PROCEDURE

A. Start-Up Procedure

1. Checks prior to turning on:
 - a. Visual inspections of analyzer / system / reagents:
 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.
 4. Verify waste tubing and floor drain is not obstructed.
 5. Verify network / host connections are properly working.
 6. Verify sufficient reagent supply is nearby.
2. Turning ON the entire system
 - a. Verify that all power switches for each device are in the ON position.
 - b. Press the power button on the IPU to power ON the entire system.
3. Log on to the XN-IPU
 - a. When the logon dialog box appears, enter user name and password.
4. Analyzers self-checks
 - a. XN: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to three 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 10 ⁶ /μL
HGB	0.1 g/dL
PLT-I	10 x 10 ³ / μL

5. Analyze quality control material

B. Patient Sample Processing

1. System Analysis (sampler 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 button if necessary.
 - c. Place sample(s) in rack(s) in right sampler pool (analyzer side).
 - d. Select Sampler - 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.

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

- h. Remove the rack from the left sampler pool when analysis is completed.
- i. Make smear if indicated.
2. Manual Analysis
 - a. Check the status of the analyzer. Confirm the analyzer is ready.
 - b. Press the mode switch to eject the tube holder.
 - c. Select the Change Analysis Mode button on the control menu.
 - d. Select analysis mode.
 1. [Whole blood] is selected when whole blood is being analyzed.
 2. [Low WBC] Select this to perform low WBC analysis on whole blood.
 3. [Pre-Dilution] select when running 1:7 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.
 1. If running microtainer, remove the cap using caution to avoid splattering.
 - j. Press the start switch on the analyzer.
 1. The tube holder will slide in and the sample will be aspirated.
 2. 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.

C. XN-1000 Clean – performed daily

1. CELLCLEAN AUTO is used to clean the entire system. Refer to the XN-1000 *Instructions for Use* for detailed illustrated procedures.
 - a. Confirm analyzer and sampler unit are at ready.
 - b. Place analyzer in manual mode and confirm the tube holder is ejected from the analyzer.
 - c. Place 1 tube of CELLCLEAN AUTO in tube holder.
 - d. Place rack on sampler unit. Select Sampler-Start.
 - e. XN on-board maintenance history will auto-populate. The BACKGROUNDCHECK will be automatically performed and the analyzer will then go into READY mode.

D. XN-1000 Shutdown – performed weekly

1. CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-1000 *Instructions for Use* for detailed illustrated procedures.

**Complete Blood Count (CBC) and WBC Differential Analysis on the
XN1000R**

- a. Confirm analyzer and sampler unit are at ready.
- b. Confirm tube holder is retracted into the analyzer.
- c. Obtain empty rack.
 1. Place 1 tube of CELLCLEAN AUTO in rack, position 10. This rack will shut down the XN. IPU will automatically shut off at the conclusion (approx. 15min).
- d. Place rack on sampler unit. Select Sampler-Start.
- e. XN on-board maintenance history will auto-populate.
- f. Press the power button on the IPU to initiate the 'Start-up' sequence. The BACKGROUNDCHECK will be automatically performed and the analyzer will then go into READY mode (approx. 8-9 min).

E. Maintenance

1. Maintenance performed on the XN will be automatically tracked in the maintenance history.
2. Refer to the XN's *Instructions for Use* for 'as needed' maintenance.

VII. PROCEDURAL NOTES AND CALCULATIONS

- A. All calculations necessary for obtaining final results are automatically performed on the XN analyzer.
- B. If making a dilution of a patient specimen and running in XN Whole Blood mode, multiply the parameters by the dilution factor.
- C. If correcting the HGB or HCT due to interfering substances, recalculate and correct the affected indices:
 1. $MCHC = HGB / HCT \times 100$
 2. $MCH = HGB / RBC \times 10$
 3. $MCV = HCT / RBC \times 10$
- D. Current on-board rules must be exported and saved on external storage device each time a change is made. A printout of the rules should be inserted in the XN-Series Resource Manual.
- E. **Do not** place samples on a mechanical rocker. Excessive mixing may alter white cell membranes resulting in false interpretive messages.
- F. For troubleshooting specifics refer to the XN's *Instructions for Use*.

VIII. REPORTING RESULT

- A. Reference Ranges are reported with each result.
- B. All STAT results are to be reported within 40 minutes.

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

- C. All routine results are to be reported within 4 hours.
- D. All CBC orders with **manual differential** (CBCMD) will require that a differential and morphology be performed on the specimen.
- E. All CBC orders with **no differential** (CBCND) will have no manual differential or RBC morphology generated. Please Note: **All CBC's with no differential will have a platelet estimate performed if the platelet count from the analyzer is <100.000 X10^{~3}/μL.** This result can be entered under the Enter Result function.
- F. All CBC orders with **automated differential** (CBCAD) will have to have their criteria evaluated before results are reported. If the specimen does not need to have a manual differential or a RBC morphology scan performed, the technologist must answer the Morphology and Differential queries on the Process Analyzer Batch screen. The results would be a Normal Morphology and Adequate Platelet
- G. Reference Ranges

TABLE: HSL-010.01 CBC Reference Ranges

ANALYTE	AGE	NORMAL RANGE BOTH SEXES	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

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	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

Complete Blood Count (CBC) and WBC Differential Analysis on the XN1000R

	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			pcG
	7-59 DAYS	28-40			pcG
	2MO-5MO	26-34			pcG
	6MO-23MO	23-31			pcG
	2YR-5YR	24-30			pcG
	6YR-11YR	25-33			pcG
	12YR-17YR	25-35			pcG
	ADULT	26-34			pcG
MCHC	0-2 DAYS	30-36			G/dL
	3- 6DAYS	29-37			G/dL
	7-29 DAYS	28-38			G/dL
	1MO-5MO	29-37			G/dL
	6MO-23MO	30-36			G/dL
	2YR-ADULT	31-37			G/dL
RDW	ALL	11.5-14.5			%
PLT	ALL	130-400			X10~3 uL
MPV	ALL	7.4-10.4			fL

IX. REPORTING ABNORMAL RESULTS TO PHYSICIANS

- A. All critical values will be reported to the appropriate patient care personnel. Please review the Critical Value Policy for proper notification/documentation. LAB-106-P.
1. Repeat testing of the original specimen. After determining that the result is correct, the critical value will be called to the appropriate caregiver.

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This result must be repeated back to the laboratory testing personnel and documented in the Laboratory LIS system.

- B. All technologists must be familiar with the criteria stating when to perform an RBC morphology scan, platelet estimate, manual differential or to leave the peripheral blood smear for the pathologist to review.
- C. Document specimen rejections and notify client / patient for a recollect.

X. CRITERIA for performing a MANUAL DIFFERENTIAL

- A. If any of the criteria below are met, a manual white blood cell differential must be performed on a specimen that is ordered as a CBC with automated diff. (CBCAD)

Criteria for Ordering a Manual Differential	
WBC <2.0 mm ³	<2.0 mm ³
Neutrophil #	>20.0
Lymphocyte Absolute #	>5.0 (5000)
Monocyte Absolute #	>1.5 (1000)
Eosinophils Absolute #	>1.5 (1000)
Basophils Absolute #	>1.0 (1000)

- B. All LS flags (Left Shift) of 2+,3+ send to main lab for a manual differential
- C. All IG flags (Immature Granulocytes) of 2+,3+ send to main lab for a manual differential
- D. All MPO (Myeloperoxidase deficiency: granulocytes will be 0 or very low; lymphocytes and monocytes will be very high) send to main lab for a manual differential. The automated differential from the analyzer should **NOT** be reported. ('NP' the results). Answer "NO" to report differential in the analyzer screen.
- E. All Blast flags send to main lab for a manual differential
- F. All Atypical Lymphocytes send to main lab for a manual differential
 - **Please note:** A manual differential is performed on all specimens of children less than 6 years of age. The automated differential result is NOT reported.

XI. CRITERIA for review of RBC MORPHOLOGY

- A. If any of the criteria below are met, send to main lab for a review of red blood cell morphology on a specimen that is ordered as a CBC with automated diff. (CBCAD)

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Criteria for Ordering a RBC Morphology	
Hct	<25%
MCV	<70 or >110
RDW	>22
Hypo, Aniso, Micro, Macro	2+, 3+ analyzer flags

XII. CRITERIA for review of PLATELET COUNTS

- A. If any of the criteria below are met, send to main lab for a manual platelet estimate of the peripheral blood smear on a specimen that is ordered as a CBC with automated diff (CBCAD) and CBC No diff (CBCND).
- Manual platelet estimates that are performed for a CBCND are entered under the result entry screen

Criteria for performing Peripheral Platelet Estimate	
Platelets	<100,000 mm³ or >700,000 mm³

XIII. CRITICAL VALUES

TABLE: HSL-010.02 Critical Values

Test	Units of Measure	Critical Low	Critical High
WBC*	x10 ³ /μL	Less than 2.0	Greater than 35
Neonatal WBC (0-7 days)	x10³/μL	Less than 2.0	Greater than 50
Hemoglobin	g/dL	Less than 7.0	N/A
Neonatal Hemoglobin	g/dL	Less than 9.5	Greater than 25
Hematocrit	%	Less than 20.0	N/A
Neonatal Hematocrit	%	Less than 29.0	Greater than 75
Platelets*	x10 ³ /μL	Less than 50	Greater than 1,000

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XIV.LIMITATIONS OF PROCEDURE

A. XN-Series Manufacturer Stated Linearity

1. Parameters that exceed these limits are flagged with '@' beside the result. The sample must be sent to the main lab to be diluted, rerun and multiplied by the dilution factor.
2. Note the use of dilution for linearity on the patient report.

Parameter	Range	Units
WBC	0-440.0	x10 ³ /μL
RBC	0-8.60	x10 ⁶ /μL
HGB	0-26.0	g/dL
HCT	0-75.0	%
PLT	0-5000	x10 ³ /μL
RET%	0-30	%
NRBC%	0-600	/100 WBC

B. Possible Sample Interferences

1. Specimens must be free of clots and fibrin strands.
2. Marked changes in plasma constituents (e.g., low sodium, extremely elevated glucose) may cause cells to swell or shrink. The blood to anticoagulant ratio is important.
3. Red cell fragments, microcytic RBC's or white cell cytoplasmic fragments may interfere with automated platelet counts. A fluorescent platelet may be performed to avoid this interference if available in the Spohn Shoreline main lab.
4. Cold agglutinins produce spurious macrocytosis, elevated MCH's, MCHC's, falsely decreased RBC counts and HCT's. Rare warm agglutinins produce the same spurious results as a cold agglutinin.
5. Extremely elevated WBC's may cause turbidity and falsely increase the hemoglobin, RBC and HCT values.
6. Severely hemolyzed samples (*in vitro*) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
7. Giant platelets and clumped platelets may falsely elevate the WBC count and falsely decrease the platelet count. 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. If "platelet satellitism" is due to EDTA, send unspun sodium citrate whole blood and EDTA sample to Spohn Shoreline main lab for testing.

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8. Abnormal paraproteins found in blood from patients with Multiple Myeloma can falsely increase the HGB. Send the specimen to the main lab to correct HGB by performing plasma replacement.
9. Severely icteric samples may falsely elevate the HGB value and related indices. Send specimen to the Shoreline main lab to make a 1:5 dilution with CELLPACK or other alternative procedure.
10. Rocking specimen excessively, may affect the WBC differential.
11. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.

XV. REFERENCES

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XN1000R**

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Effective Date for this procedure:

8/27/2018

Revised by:

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