Status **Pending** PolicyStat ID **17744501**

Origination	N/A
Last Approved	N/A
Effective	Upon Approval
Last Revised	N/A
Next Review	2 years after approval
Owner	Carolyn Webb: Heme Technical Specialist
Area	Hematology
Applicability	Community Physician

Xn-1000 / Xn-2000 Operation and Maintenance

SCOPE

Sysmex XN-1000™ (XN-10/XN-20) and Sysmex XN-2000™ (XN-10/XN-20) effective 3/19/25 at

- Drexel Town Square Health Center
- Moorland Reserve Health Center
- Town Square Health Center
- West Bend Health Center

PRINCIPLE

I. The XN series analyzers (XN-10, XN-20) are analytical modules of the XN-1000 XN-2000 systems. The XN-1000 XN-2000 analyzers are multi-parameter quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 32 whole blood diagnostic parameters and 7 body fluid parameters. Examination of the numerical and/or morphological findings of the complete blood count by the physician are useful in the diagnosis of disease states such as anemias, leukemias, allergic reactions, viral, bacterial, and parasitic infections. (Note: Body fluids are not performed at any CP lab.)

II. The analyzer performs hematology analysis according to the hydrodynamic focusing (DC Detection), flow cytometry method (semiconductor laser), and SLS-hemoglobin method.

III. The device counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection (sheath flow DC method). 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.

IV. The white blood cell (WBC) count, differential (DIFF), reticulocyte parameters (RET), fluorescent platelet (PLT-F), 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.

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

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

SPECIMEN REQUIREMENTS

Preferred specimen

Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.

Acceptable specimen

Sodium citrate is only acceptable for platelet count when platelet clumping is observed in the EDTA sample. Sodium citrate is not an FDA approved sample and this sample type has been validated by Froedtert health system laboratories.

COLLECTION AND PROCESSING INSTRUCTIONS:

A. There are no special instructions for patient preparation or specimen collection

B. Allow refrigerated samples to come to room temperature and mix well before analysis.

C. CBC and Diff samples may be placed on a mechanical rocker for a maximum of 15 minutes. Constant rocking may alter white cell membranes, resulting in false interpretive messages.

D. Samples analyzed within 4 hours of collection do not require external mixing when autosampler is used.

E. All samples processed via manual sampler must be hand-mixed by ten inversions prior to placing tube on analyzer.

MINIMUM VOLUME:

A. Specimen volumes required

   1. Optimal draw is a 12 x 75 mm tube filled to capacity. Minimum volume = 1 mL
   2. Microtainer optimal volume = 500 µL, Minimum volume = 250 µL

B. The analyzer aspirates 88 µL regardless of tube type or sampling mode.

C. Do NOT use the predilute mode on the XN analyzer to try to salvage samples with volumes less than 1mL in 12x75 mm tube or less than 250 uL in a microtainer tube.

Stability

Temperature	Time
Ambient	8 hours

Refrigerated	24 hours
Frozen	Unacceptable

Unacceptable specimens:

- Those containing fibrin or clots
    - XN systems provide flagging identify samples with platelet clumps or fibrin. Checking for fibrin/cots is only required when flags are present or when microtainer samples are being processed.
- Hemolyzed samples
    - Hemolyzed specimens are identified by failed H&H check
- Expired or improperly stored collection tubes
- Tubes with less than the minimum specimen volume
- Specimens contaminated with IV fluid

Characteristics that may affect test results that do not require specimen rejection:

See Hematology Problem Specimen Handling procedure for how to handle these specimens

A. Lipemia
B. Icterus
C. Hemolysis
D. Cold agglutinins

SAFETY

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

MATERIALS

Supplies

A. Test tubes
B. CELLCLEAN™ AUTO
C. Sysmex reagents
D. Commercial Quality Controls: XN CHECK™
E. See also “Frequently Used Consumables” document on Sysmex Customer Resource Center (CRC).

Reagents

General Information

A. Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-Series modules.

B. All reagents are used at room temperature and are to be used within the manufacturer's expiration date on each container.

C. Record date received and date opened on container.

D. All reagents are azide free and are intended for *in vitro* diagnostic use only. **Do not ingest.**

XN-10/XN-20 REAGENTS

Diluents

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

1. CELLPACK DCL Storage
    a. Store at 2-35°C away from direct sunlight.
    b. If frozen, thaw and mix thoroughly before using. Allow bubbles to dissipate before using.
2. CELLPACK DCL is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.
3. CELLPACK DCL Stability
    a. Unopened, it is stable until expiration date printed on the container.
    b. Opened, stable for 60 Days.
4. CELLPACK DCL Hazard Risk - non-hazardous

B. CELLPACK DST (DST): **NOTE:** DST requires the RU-20 Reagent preparation unit. Applicable to Drexel and Moorland only.

1. 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 been frozen.
2. CELLPACK DST is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.
3. CELLPACK DST Stability
    a. Unopened, it is stable until expiration date printed on the container.Opened, stable for 60 Days.
4. CELLPACK DST Hazard Risk - non-hazardous

C. CELLPACK DFL (DFL): Whole blood diluents for use in hematology analyzers; used in combination with Fluorocell™ RET for the analysis of reticulocytes, or with Fluorocell PLT for the analysis of platelets by flow cytometry method using a semiconductor laser.

1. CELLPACK DFL StorageStore at 2-35°C away from direct sunlight.
2. Do not use the reagent if it is suspected to have been frozen.
3. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.

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

E. CELLPACK DFL Hazard Risk - non-hazardous

Lysing Reagents

A. 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.
    1. 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. If frozen, thaw and mix thoroughly before using.
        d. Replace the reagent if it is showing signs of contamination or instability such as cloudiness or discoloration.
    2. SULFOLYSER Stability
        a. Unopened, it is stable until expiration date printed on the container.
        b. Opened, it is stable for 60 Days (1.5L) or 90 Days (5L).
    3. SULFOLYSER Hazard Risk - non-hazardous

B. 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.
    1. 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.
    2. Lysercell WNR Stability
        a. Unopened, it is stable until expiration date printed on the container.

b. Opened, it is stable for 60 Days.

3. Lysercell WNR Hazard Risk - non-hazardous

C. 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.

1. 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.
2. Lysercell WDF Stability
    a. Unopened, it is stable until expiration date printed on the container.
    b. Opened, it is stable for 90 Days.
3. Lysercell WDF Hazard Risk - non-hazardous

D. Lysercell WPC: Reagent product to be combined and used with Fluorocell WPC. Lysercell WPC hemolyzes red blood cells and Fluorocell WPC detects the possible presence of abnormal or immature cells. (Used on XN-20 only. Applicable only to Drexel and Moorland)

1. Lysercell WPC 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.
2. Lysercell WPC Stability
    a. Unopened, it is stable until expiration date printed on the container.
    b. Opened, it is stable for 90 Days.
3. Lysercell WPC Hazard Risk - non-hazardous

Staining Reagents

A. 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.

1. 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.

2. Fluorocell WNR Stability
    a. Unopened, it is stable until expiration date printed on the container.
    b. Opened, it is stable for 90 Days.
3. Fluorocell WNR Hazard Risk - Refer to the SDS.
    a. Hazard identification
        i. Harmful if swallowed
        ii. May cause damage to the kidneys through prolonged or repeated exposure.
        iii. Route of exposure: Oral
    b. Hazard Precautions
        i. Do not breathe mist/vapors/spray.
        ii. Wash thoroughly after handling
        iii. Do not eat, drink or smoke when using this product
        iv. If Swallowed: Call a Poison Center/doctor if you feel unwell
        v. Get medical advice/attention if you feel unwell
        vi. Rinse mouth.
    c. Dispose of excess product as a hazardous waste. Do not pour excess reagent down the drain.

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

1. 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.
2. Fluorocell WDF Stability
    a. Unopened, it is stable until expiration date printed on the container.
    b. Opened, it is stable for 90 Days.
3. Fluorocell WDF Hazard Risk -Refer to the SDS.
    a. Hazard identification
        i. Harmful if swallowed
        ii. Harmful if inhaled
        iii. May cause damage to organs
    b. Hazard Precautions
        i. Wash face, hands and any exposed skin thoroughly after handling
        ii. Do not eat, drink or smoke when using this product

iii. Use only in a well-ventilated area

iv. Do not breath vapors

c. Dispose of excess product as a hazardous waste. Do not pour excess reagent down the drain.

C. Fluorocell RET: Used to stain the reticulocytes in diluted blood samples for the assay of reticulocyte count, reticulocyte percent in blood.

1. 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 been frozen.

2. Fluorocell RET Stability

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

b. Opened, stable for 90 Days.

3. Fluorocell RET Hazard Risk - Refer to the SDS.

a. Hazard identification

i. Flammable liquid and vapor

ii. Harmful if swallowed

iii. Harmful in contact with skin

iv. Harmful if inhaled

v. May cause damage to the central nervous system and optic nerve

vi. May cause damage to the kidneys through prolonged or repeated exposure. Route of exposure: Oral

b. Hazard Precautions

i. Keep away from heat/sparks/open flames/hot surfaces. No smoking.

ii. Use explosion-proof electrical/ventilating/lighting/equipment

iii. Do not breathe mist/vapors/spray

iv. Wash thoroughly after handling

v. Wear protective gloves/protective clothing/eye protection

vi. Keep container tightly closed

vii. Use only non-sparking tools

viii. Take precautionary measures against static discharge

ix. Use only in a well-ventilated area

x. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

xi. If Inhaled: Remove person to fresh air and keep comfortable for breathing

xii. Wash contaminated clothes before reuse

xiii. If swallowed: Call a poison center/doctor if you feel unwell
xiv. Rinse mouth
xv. In case of fire: Use CO2, powder or water spray for extinction
xvi. If exposed or concerned: Call a Poison Center/doctor
xvii. Store locked up
xviii. Store in a well-ventilated place. Keep cool

c. Dispose of excess product as a hazardous waste. Do not pour excess reagent down the drain

D. Fluorocell PLT: Used to stain the platelets in diluted blood samples for the assay of platelet counts in blood.
    1. 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.
    2. Fluorocell PLT Stability
        a. Unopened, it is stable until expiration date printed on the container.
        b. Opened, stable for 90 Days.
    3. Fluorocell PLT Hazard Risk - Refer to the SDS
        a. Hazard Identification
            i. Harmful if swallowed
            ii. May cause damage to the kidneys through prolonged or repeated exposure. Route of exposure: Oral
        b. Hazard Precautions
            i. Do not breathe mist/vapors/spray
            ii. Wash thoroughly after handling
            iii. Do not eat, drink or smoke when using this product
            iv. If swallowed: call a Poison Center/doctor if you feel unwell.
            v. Rinse mouth
        c. Dispose of excess product as a hazardous waste. Do not pour excess reagent down the drain

E. Fluorocell WPC: Used to stain the leukocytes in diluted and lysed blood samples for detection of various immature cells in blood. **NOTE**: ***(XN-20 only)***
    1. Fluorocell WPC Storage
        a. Store at 2-35°C in a dark place.
        b. Do not use the reagent if it is suspected to have frozen.
    2. Fluorocell WPC Stability
        a. Unopened, it is stable until expiration date printed on the container.

b. Opened, it is stable for 90 Days.

3. Fluorocell WPC Hazard Risk - Refer to the SDS.
    a. Hazard Identification
        i. Flammable liquid and vapor
        ii. Harmful if swallowed
        iii. May cause damage to the kidneys through prolonged or repeated exposure. Route of exposure: Oral
    b. Hazard Precautions
        i. Keep away from heat/sparks/open flames/hot surfaces. No smoking.
        ii. Use explosion-proof electrical/ventilating/lighting/equipment
        iii. Do not breathe mist/vapors/spray
        iv. Wash thoroughly after handling
        v. Wear protective gloves/protective clothing/eye protectio
        vi. Keep container tightly closed
        vii. Use only non-sparking tools
        viii. Take precautionary measures against static discharge
        ix. Do not eat, drink or smoke when using this product
        x. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
        xi. If swallowed: Call a poison center/doctor if you feel unwell
        xii. Get medical advice/attention if you feel unwell
        xiii. Rinse mouth
        xiv. In case of fire: Use CO2, powder or water spray for extinction
        xv. Store in a well-ventilated place. Keep cool
    c. Dispose of excess product as a hazardous waste. Do not pour excess reagent down the drain

Cleaning Agent

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

1. **CELLCLEAN AUTO Storage**
    a. Store at 1-30°C, away from direct sunlight.
    b. Do not use the reagent if it is suspected to have frozen.
2. CELLCLEAN AUTO Stability
    a. Unopened, it is stable until expiration date printed on the container.

b. Single use vials

3. CELLCLEAN AUTO Hazard Risk - Refer to the SDS
    a. Hazard Identification
        i. **DANGER:** CELLCLEAN AUTO is corrosive
        ii. May cause severe skin burns and eye damage
    b. Hazard Precautions
        i. If exposure occurs, immediately call a Poison Center or doctor.
        ii. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
        iii. If on skin or hair: Take off immediately all contaminated clothing. Rinse skin with water [or shower]
        iv. Wash contaminated clothing before reuse
        v. If inhaled: Remove person to fresh air and keep comfortable for breathing
        vi. If Swallowed: Rinse mouth. Do NOT induce vomitting
        vii. Store locked up
    c. Dispose of excess product as a hazardous waste. Do not pour excess reagent down the drain. Extremely toxic to fish.

OPEN EXPIRATION Summary

XN REAGENTS	OPEN EXPIRATION
CELLPACK™ DCL	60 Days
CELLPACK DST	60 Days
CELLPACK DFL	60 Days
SULFOLYSER™	60 Days (1.5L) 90 Days (5.0L)
Lysercell™ WNR	60 Days
Fluorocell™ WNR	90 Days
Lysercell WDF	90 Days
Fluorocell WDF	90 Days
Fluorocell RET	90 Days
Fluorocell PLT	90 Days
Lysercell WPC ***(XN-20 only)***	90 Days
Fluorocell WPC ***(XN-20 only)***	90 Days
CELLCLEAN AUTO	Single Use Vial

INSTRUMENT SETTINGS:

Analyzers are setup so the definitive flagging matches Caresphere rules. There are no rules active in the analyzer. Refer to Caresphere procedure for rule details.

CALIBRATION

FREQUENCY:

Initial analyzer precision and calibration is performed during installation by the Sysmex Service Engineer (SE). Calibrators traceable to reference methods are used in the calibration of the analyzer.

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

Calibration of an analyzer should only be completed when:

- Installation activity occurs.
- Calibration Verification fails after critical dilution or analytical parts and assemblies are replaced. The XN critical parts are:
    - Pipettor assembly
    - Flow Cytometry Module (FCM) Detector Block
    - RBC Detector Assembly
    - Hemoglobin Detector Assembly
- Calibration Verification fails (QC values are outside of acceptable limits) and troubleshooting indicates that there is no major underlying problem with the analyzer, reagents or quality control materials.
- Advised by a Sysmex Representative.

Call technical assistance center 1-888-879-7639 any time it is suspected that calibration may be needed. Calibration is performed by Sysmex service engineer.

Calibration verification is continually performed via Beyond Care Quality Management system (BCQM).

MATERIALS:

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

STABILITY:

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

PREPARATION: not applicable to bench tech

ACCEPTABILITY: determined by service engineer

Calibration Verification

A. Calibration verification following replacement of parts is accomplished by running at least 2 levels of QC and obtaining acceptable results.

B. In lieu of 6-month calibrations the CCV Certificate Report will be reviewed monthly. CCV Certificate report is an on-demand report for accuracy and precision of the test method that follows CLIA recommendations for automated cell counters verification of calibration (using approved standards for cal verification).

QUALITY CONTROL (QC)

FREQUENCY:

CP labs are set up in BCQM to require 3 levels of control every 8 hours of patient testing.

It should be noted that for troubleshooting purposes, additional control runs may be necessary. The BeyondCare Quality Monitor program will help determine when troubleshooting is necessary and dynamic screen prompts will guide the end user for the next action. All troubleshooting actions are logged in the Activity Log. *(Refer to the BeyondCare Quality Monitor IFU for full details.)*

MATERIALS:

A. **Commercial Quality 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 all XN analyzers.

c. Formulation

i. XN CHECK Consists of human red and white blood cells with a platelet component suspended in fluid medium.

ii. Each vial contains 3 mL of control material.

d. Storage

i. Store vials at 2-8^{O}C

ii. Do not freeze or expose to excessive heat.

e. Stability

i. Unopened and properly stored, XN CHECK is stable until the expiration date printed on the unopened vial.

ii. Open vial stability is 7 days for XN CHECK when promptly refrigerated after each use.

iii. Record the date opened and the open expiration date on each vial upon initial use.

iv. 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.

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

f. **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.

QC ANALYSIS

XN Check QC Analysis

A. XN CHECK Commercial Quality Controls Instructions for Use:

1. Remove vials from the refrigerator and allow them to come to room temperature (18-25°C), for approximately 15-30 minutes.
2. Mix vials according to the package insert accompanying the product until the cell button in the bottom of the vial is completely suspended.
3. If an XN-2000 configuration is present, XN CHECK Quality Control vials tested in the sampler rack mode will travel to both XN analyzers.

B. XN CHECK QC Analysis

1. Place the vial containing control blood in the rack.
2. Place rack on sampler unit; sampler will auto-start on XN-2000. XN-1000 may require you to press the START button no the IPU Screen.
3. If an XN-2000 configuration is present, XN CHECK Quality Control vials tested in the sampler rack mode will travel to both XN analyzers.
4. Results will automatically be sent to ***Insight*** and the BCQM^h program.

ACCEPTABILITY:

Reviewing Quality Control Results in BeyondCare Quality Monitor

A. The BCQM^h program allows the user to customize QC analysis preferences for QC analysis into the program. The program can be accessed by logging into https://ccv.sysmex.com.

1. **Drexel ID**: 80060@bcqm.com

Password: bcqm1234

2. **Moorland ID:** 81508@bcqm.com
   Password: bcqm1234
3. **Town Hall ID:** 81107@bcqm.com
   Password: bcqm1234
4. **West Bend Health Center ID**: 82829@bcqm.com **Password:** bcqm1234

B. The BCQM^h Dashboard will notify the user as to when QC analysis is required and if that analysis falls within the acceptable limits. The dashboard colors are:

1. **Green –** All control requirements have been met. Analyzer is Ready for patient analysis.
2. **Yellow –** indicates additional action/information is required. Follow onscreen steps for returning to analysis ready.
3. **Red** – Indicates service is required due to a detected issue not resolved by recommended corrective action.
4. **Resolve –** is activated if a QC error has been detected. Follow prompts to the next course of action. The instructions button gives details on how to perform the troubleshooting action. **If Resolve button appears, it must be pressed within 45 minutes of appearing.** If Resolve is not pressed you will need to contact Sysmex Technical Assistance Center to reset the analyzer and perform troubleshooting 1-888-879-7639 (1-888-8SYSMEX).
5. **QC is overdue –** end user needs to analyze QC since it exceeds the timeframe determined by the preferences screen.
6. For a calendar view of whether the QC passed or failed, access the Summary report which will also display background status,
   a. P = Last 2 different levels of QC passed
   b. F = QC failed
   c. B = Background counts pass
   d. X = Background counts failed
   e. ? = Run QC
   f. L = XNBF QC passed
   g. D = XNBF QC failed
   h. S = service event
   i. Calibration (EBC)
7. ***Follow the BeyondCare Quality Monitor for troubleshooting Quality Control results exceeding the upper or lower limit of acceptability.*** BCQM provide troubleshooting instructions with access to step by step instructions for maintenance procedures needed to resolve the QC failure.
   a. BeyondCare Quality Monitor will automatically not manage (exclude) a QC run if a corrective action has taken place and the same QC level is repeated and falls within the BeyondCare Quality Monitor specification limits. An “SM” (system managed) symbol will appear next to the raw data in the ***Insight*** report. No QC runs are ever deleted.

b. If the QC reviewer decides to manage (include data in calculations) or not manage (exclude data from calculations the BeyondCare Quality Monitor application), log into ***Insight*** (www.sysmex.com/Insight) and select Review QC data which will allow QC data management by the ***Insight*** user. A comment must be added when manually changing data from managed or not managed.

REVIEW of QC DATA when BCQM is NOT AVAILABLE

A. In the event SNCS (Sysmex network communication system) loses connection Beyond Care Quality Monitor becomes unavailable until SNCS connection is restored.

B. Review the QC files on the analyzer IPU. Results are automatically plotted on radar charts and on Levy-Jennings charts.
    1. Radar charts [QC FILE] show a summary of a single control run
    2. Levy-Jennings charts [QC CHART] show the trends of the control results over time

C. Document corrective action in comments in IPU when BCQM is not available
    1. In the [QC Chart] screen, move the cursor to the desired analysis result.
    2. Touch the [Manage] button - [Cursor Data Mangement}] on the toolbar. The [Cursor Data Mangement] dialog box appears.
    3. Touch an item to set the condition
        a. [Specify Excluded]
            i. Manage= include data in statistical calculations
            ii. Not Managed = Exclude data from statistical calculations (exclude all failed QC runs that have been corrected by corrective actions)
        b. [Comments Settings]
            i. Chose [Input Any Comment] and type in the corrective action taken along with your initials in the [Any Comments] box.
            ii. If [QC Chart Fixed Comments] are available, canned comments may be selected to document corrective action if appropriate.
            iii. Comment cannot be added if [None] is selected
    4. Touch OK

QC CORRECTIVE ACTION

BCQM provides standardized instructions for troubleshooting failed QC results. Techs follow the instructions provided by BCQM and the corrective actions are automatically recorded based on the actions taken.

See instructions above for documenting corrective action when BCQM is not available.

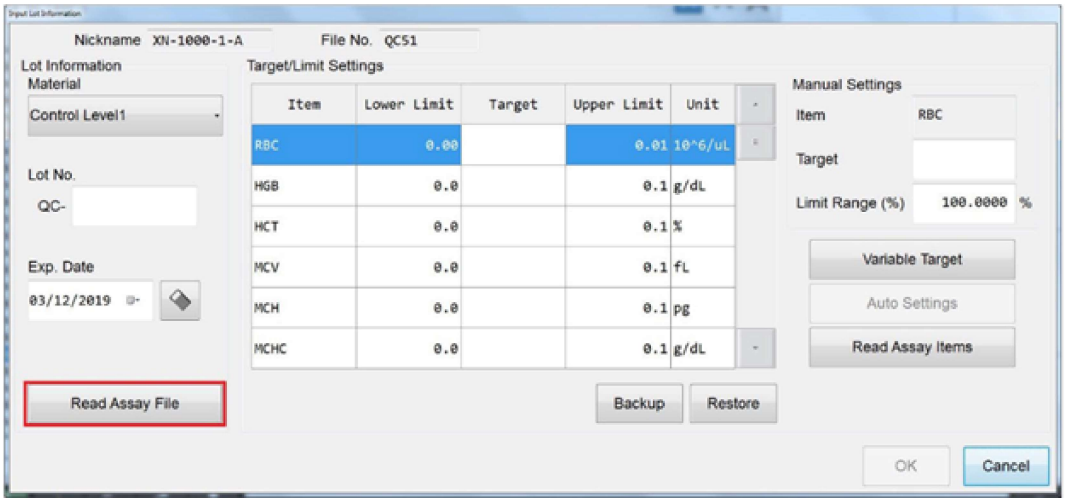
NEW LOTS OF QC MATERIALS

Registration of new lot of QC material

A. The procedure for registering QC material in XN analyzers using the targets/limits from the BCQM

application is as follows:

1. Select [QC File] icon from XN-Series IPU Main Menu.
2. Select a QC file that does not have a lot registered. Choose empty spaces that allows three controls to be registered in sequence.
3. Select [Register].
4. Select [Read Assay file]. NOTE: If no lot numbers are listed in the "Select Lot" list, continue beginning with Step 5 below. If the "Select Lot" list contains lot numbers, skip to Step 8.



5. Select "Browse" on the Read Assay File screen
6. The "Insert Disc" dialog box will appear. Select "Cancel".
7. The "Browse for Folder" Dialog box will appear. Navigate to the "BCQM Target Limits" folder on the Desktop. Select "OK" and the lot numbers will be populated in the "Select Lot" list.
8. Select the desired lot/level for the file you are setting up, then select "OK".
9. The Targets and Limits will automatically populate. Select "OK".
10. Verify the QC lot number, level and expiration date matches the QC vials received by the lab.
11. Repeat for each level of QC material to be registered.
12. NOTE: It is expected that the targets and % limits obtained from the BCQM database will be different than the published Sysmex Evidence Based QC limits and the QC Product Assay Sheet.

New QC lot crossover or parallel studies

As soon as the new QC lot is received, the new lot is analyzed in conjunction with the current QC. The BeyondCare Quality Monitor program establishes the target and limit values for the new QC lot as soon as the first vial of each level gets analyzed.

New lot must be run 10 times before it is used as the active lot. This may be accomplished by running the control once a day for 10 days or twice a day for five days.

Recording and Storage of QC Data

A. **Review of QC Data**

1. QC is reviewed daily by performing tech.
2. The following reports should be reviewed by key operator, technical specialist, supervisor, or manager. See Hematology Quality Management policy for details:
    a. ***Insight*** *Report (This report shows exceptions that need to be reviewed and actions needed. Insight is generated after 1st half and conclusion of a control lot.)*
    b. *Detailed Daily Verification Report (This report shows how the QC results are trending on a day to day basis. All three levels of control are plotted on the same graph for each individual component.)*
    c. *Continuous Calibration Verification Certificate (This report shows lab mean vs target mean)*

B. Storage of QC Data

1. The BeyondCare Quality Monitor application stores the last 2.5 years of QC data on demand. All QC data older than 2.5 years is archived. If data older than 2.5 years is needed, contact Sysmex Technical Assistance Center.
2. If no comments are needed on the report, it can be reviewed electronically in BCQM. Once these reports have been reviewed through the BeyondCare Quality Monitor application, they can be accessed by going to Activity _ Reviewed Documents. Reports are archived for 2.5 years in BeyondCare Quality Monitor. Reports that are older than 2.5 years can be attained by contacting Sysmex Technical Assistance Center.
3. If comments need to be documented on a report, the report is downloaded, saved on a shared drive on Froedtert's network and retained for a minimum of 2 years.

MAINTENANCE

DAILY MAINTENANCE

A. **XN-10/XN-20 Shutdown –** performed daily at end of day

1. CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-1000/ XN-2000 *Instructions for Use* for detailed illustrated procedures.
2. Confirm analyzer and sampler unit are at ready.
3. Confirm tube holder is retracted into the analyzer.
4. Obtain empty rack.
5. XN-1000 - 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.
   XN-2000 – Place 1 tube of CELLCLEAN AUTO in rack position 10 (right analyzer) and 1 tube in rack position 9 (left analyzer) to shutdown both analyzers.
6. Load the rack on the right sampler pool.
7. Shutdown is performed automatically.

8. The Analyzer[s] and the IPU will automatically power off once the Shutdown sequence is complete.
9. Remove the rack or tube[s] of CELLCLEAN AUTO. XN on-board maintenance history will auto-populate.
10. ***CAUTION:***
    Use one vial of CELLCLEAN AUTO for each instrument. Do not reuse CELLCLEAN AUTO that has previously been used.
    During Shutdown, other sample tubes are not accepted.

AS NEEDED MAINTENANCE

XN analyzer or BCQM will prompt operator if 'as needed' maintenance is required. Refer to attached XN-Series Troubleshooting Manual for ‘as needed’ maintenance. All maintenance performed on the XN will be automatically tracked in the analyzer's maintenance history.

XN Reagent Replacement

When the reagent runs out during analysis, the analysis is paused and an error message appears in the analyzer area of the Control menu.

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.

Replacing CELLPACK DST with an RU-20

See Separate procedure for Sysmex RU-20 Reagent Unit Operation and Maintenance.

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.

    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.

CAUTION:

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

Upon successful completion of a reagent replacement, reagent information is automatically stored in the **Reagent Replacement Log** located in the **History icon** on the Main Menu.

Troubleshooting

For troubleshooting specifics refer to the XN-1000/XN-2000 *Instructions for Use*.

OPERATING PROCEDURE

Start-Up Procedure

A. Checks prior to turning on:
    1. Visual inspections of analyzer / system / reagents.
    2. Remove any items that may interfere with operations.
    3. Verify network / host connections are properly working.
    4. Verify sufficient reagent supply is nearby.

B. Start-Up 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.

C. Log on to the XN-IPU
a. When the logon dialog box appears, enter user name and password. (default user name = XN, no password)

D. Analyzers self-checks
    - Initialization of the mechanical parts
    - Rinse of the hydraulic units
    - 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
WBC-P *(XN-20 only)*	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
PLT-F	3 x 10^3/ µL
WBC-BF	0.001 x 10^3/ µL
RBC-BF	0.003 x 10^6/µL

E. Analyze quality control material. See Quality Control section of this procedure.

Patient Sample Processing

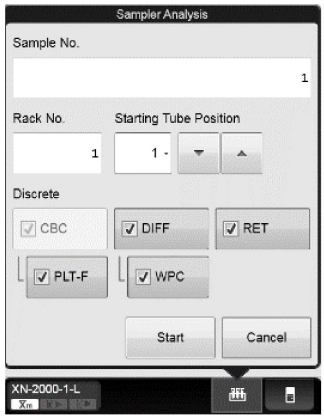
System Analysis (sampler analysis)

A. Make sure the analyzer and the sampler are in READY state.

B. Check that tube holder has retracted into the analyzer, press mode switch button on analyzer if necessary (gray button with circling arrows).

C. Place sample(s) in rack(s) in right sampler pool. Slide the groove on the rack into the protrusion on the right side (when you face the analyzer). A mximum of 5 racks can be placed.

D. Sample Analysis Start

1. XN-2000 sampler will auto-start.
    a. If an XN-2000 configuration is present, XN sample racks will be passed back and forth between both XN systems. Do not touch or interrupt the back sampling lane where racks are passed left and right. Testing and rerun processes are shared between both XN analyzers present. Allow the sample racks to be fed to the left sample pooler before removal.
2. Start XN-1000 sampler
    a. Click on the Sampler Analysis button on the control menu.
    b. 

    c. Click on [Start]. The dialog box closese, and the sampler analysis starts.

E. Samples will run, results will be displayed in the IPU and transmit to Caresphere.

F. Caresphere rules will determine repeat or reflex testing.

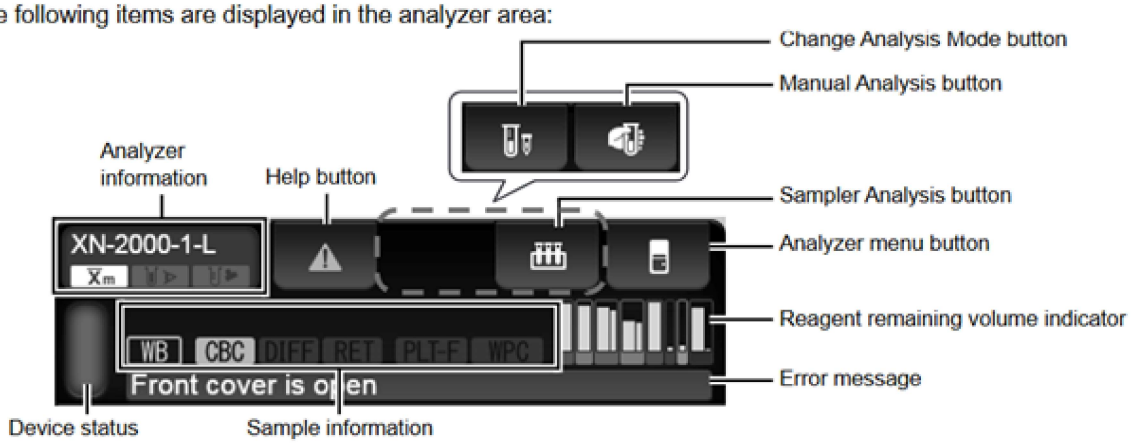
G. Remove the rack from the left sampler pool when analysis has completed.

H. Make smear if indicated.

Manual Analysis

A. Check the status of the analyzer. Confirm the analyzer is ready.

The following items are displayed in the analyzer area:



B. Press the mode switch on analyzer (Gray button with circling arrows) to eject the tube holder.

C. Select the [Change Analysis Mode] button on the control menu if not running in whole blood mode.

    1. Select analysis mode.

        a. [Whole blood] is selected when whole blood is being analyzed. This is the normal operating mode.

        b. [Low WBC] Select this to perform low WBC analysis on whole blood. Used for analyzing low WBC using whole blood. The count time of the WDF channel is set to 3 times that of [Whole blood] mode to increase white blood cell measurement accuracy. Only use this mode if Caresphere reflexed a Low WBC test.

        c. [Body Fluid] mode is NOT used in CP labs

        d. [Pre-Dilution] mode is NOT used in Froedtert labs

    2. Select [OK].

D. Select Manual Analysis button on the control menu.

E. Input sample ID or select [Read ID]. Select other options in Manual Analysis window as needed.

    1. For barcoded tube running an order that was placed in Epic or a Caresphere reflex test, select [Read ID].

    2. To run a differential on a CBC sample that requires pathologist smear review, Input sample ID manually, Select the Differential test, and leave [Query to Host] unchecked.

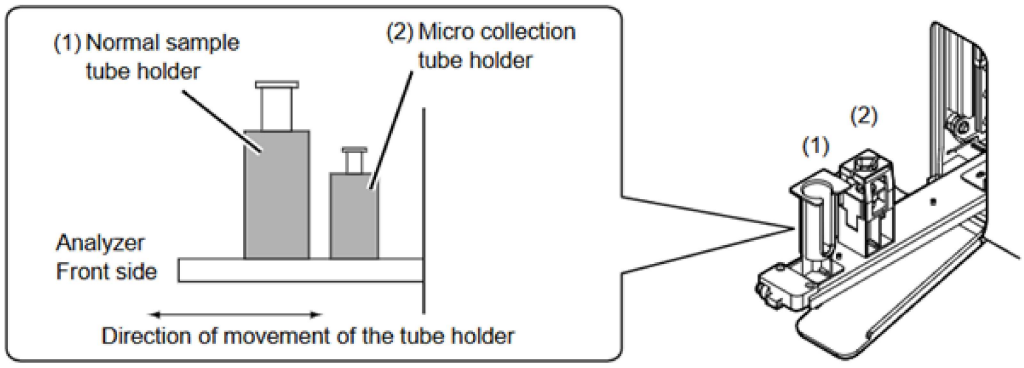
    3. [Aspiration Sensor] should always be checked.

    4. If running micro-collection tube, select ***CAP OFF.***

F. Select [OK] to close the Manual Analysis window.

G. **Properly mix the specimen** by inverting 15 times and place in the tube holder. Place sample in correct tube holder position. Keep cap on normal tubes.

    1. If running micro-collection tube, remove the cap using caution to avoid splattering**.** Check the sample for clots with sticks and place in the rear tube holder.



H. Press the start switch (blue button) 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.

I. Remove the sample, repeat steps for additional samples as needed.

J. Review results in Caresphere to determine whether repeat/reflex testing was performed or is needed or if smear review is required. See Hematology Abnormal Specimen Handling procedure for more details.

RESULT INTERPRETATION

REPORTABLE RANGE:

- **ANALYTICAL REPORTABLE RANGE:** XN Series Manufacturer Stated Reportable Range
-

Parameter	Range	Units
WBC	0.003-440.0	$x10^3/\mu L$
RBC	0.01-8.60	$x10^6/\mu L$
HGB	0.1-26.0	g/dL
HCT	0.1-75.0	%
PLT, PLT-F	2-5000	$x10^3/\mu L$
RET%	0-30	%
NRBC%	0-600	/100 WBC

- **CLINICAL REPORTABLE RANGE:**
    - Clinical reportable range is the same as analytical reportable range for the XN analyzer.
    - Do not perform dilutions on the XN analyzer.

DILUTIONS:

Dilutions are not performed at CP labs. If a dilution is required for Abnormal Retic Pattern, send the specimen to WDL.

FOLLOW UP ACTIONS

A. See Hematology Abnormal Specimen Handling procedure for details about follow up actions.

B. Flagging and Action Messages

1. Abnormal samples on the XN Series are identified using flagging systems to alert the user of a possible abnormality.
    a. Suspect flags generate a message (e.g., Atypical Lymphocyte, WBC Abnormal Scattergram). Numerical results will display an asterisk and the specimen result will display as “Positive”.
    b. Analyzer generated error codes (e.g., DIFF channel errors). Error will display in both the Browser and Explorer screens.
    c. User defined flags (e.g., leukocytosis, anisocytosis). These flags are programmable by the customer in the settings menu. When threshold limits are exceeded, a message appears, and the specimen result will display as “Positive”.
    d. Action Messages - The results are displayed in the Browser Screen.
2. Refer to the attached Sysmex XN Series Automated Hematology Systems Flagging Interpretation Guide for additional information on flagging. Do not perform any procedures described in the Flagging Guide that are not part of the Froedtert procedures found in PolicyStat.

C. Caresphere OP Alerts indicate the required follow up actions:

1. If the OP alert states it needs a MDIF, perform a manual diff
2. If the OP alert states perform manual microscopic smear, make a smear and scan for abnormalities and WBC/PLT estimates
    a. If abnormal morphology is found (WBC, RBC, or PLT) report the morphology
    b. If estimates do not confirm the analyzer count, make a new smear and recheck. If sample did not automatically reflex to PLT-F, add a PLT-F test in Caresphere and rerun the sample. Compare PLT-F count to smear estimate.
3. If the OP alert states to send fo pathology smear review, refer to the pathology smear review procedure for details about criteria before ordering and sending for pathology smear review.
4. If the OP alert states to notify another department, please notify that department
5. If the OP alert states to follow SOP, refer to Hematology Abnormal Specimen Handling Procedure

D. If Caresphere is unavailable, all suspect messages, definitive messages, and * results need follow up prior to reporting results. Refer to Hematology Downtime Procedure for details.

1. Refer to Hematology Abnormal Specimen Handling procedure and attached XN Series Flagging guide for additional guidance. Do not perform any procedures described in the Flagging Guide that are not part of the Froedtert procedures found in PolicyStat. Send specimens requiring spun HCT or dilution to WDL.

EXPECTED RESULTS:

See Hematology Reference Ranges and Critical Values procedure

LIMITATIONS

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 RBCs or white cell cytoplasmic fragments may interfere with automated platelet counts.

D. Cold agglutinins produce spurious macrocytosis, elevated MCHs, MCHCs, falsely decreased RBC counts and HCTs. Rare warm agglutinins produce the same spurious results as a cold agglutinin.

E. Extremely elevated WBCs 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”.

H. Abnormal paraproteins found in blood from patients with Multiple Myeloma can falsely increase the HGB. To correct HGB perform plasma replacement.

I. Severely icteric samples may falsely elevate the HGB value and related indices. Send sample to WDL for dilution.

J. Rocking specimen excessively, may affect the white cell membranes and cause false interpretive flags and messages. CP Laboratories have verified that 15 minutes on the rocker does not impact results..

K. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.

REFERENCES

A. Sysmex XN-1000/ XN-2000 *Instructions for Use* (North American Edition), Sysmex Corporation, Kobe, Japan.

B. Sysmex XN series *Administrator's Guide* (North American Edition), Sysmex Corporation, Kobe, Japan.

C. Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).

D. Sysmex America Inc., Mundelein, IL. XN CAL, Hematology Calibrators: Calibrators for Sysmex Hematology XN-Series Analyzers, package insert.

E. Sysmex America Inc., Lincolnshire, IL. XN CHECK Hematology Control for Sysmex XN-Series Analyzers package insert.

F. Sysmex America Inc., Lincolnshire, IL. Sysmex ***Insight*** Participant Overview Guide.

G. Koepke, John. *Practical Laboratory Hematology.* Churchill Livingstone Inc. 1991. p. 24-25, 36-39.

H. Cornbleet J., *Spurious results from automated hematology cell counters. Lab Medicine.* 1983;8:509-514.

I. Sysmex Reagents of America, Inc. SDS sheets and reagent product inserts.

J. College of American Pathologists (CAP) Hematology-Coagulation Checklist

K. Stewart, Charles and Koepke, John. *Basic Quality Assurance Practices for Clinical Laboratories*, Van Nostrand Reinhold, 1989, p 189.

L. Gulati GL, Asselta A, Chen C. *Using vortex to disaggregate platelet clumps*, Laboratory Medicine, 28:665, 1997.

M. Zhou X, Xiaoli W. *Amikacin Can Be Added to Blood to Reduce the Fall in Platelet Count*, American Journal of Clinical Pathology, 136:646-652, 2011.

N. Sysmex XN-Series Automated Hematology Systems Flagging Interpretation Guide.

O. Reagent Unit RU-20 Instructions for Use. Sysmex Corporation, Kobe Japan

P. CLSI document H56-A – Body Fluid Analysis for Cellular Composition; Approved Guideline. Vol 26, No 26

Q. 17. BeyondCare^{SM} Quality Monitor for Hematology Instructions for Use

R. 18. BeyondCare^{SM} Quality Monitor for Hematology Inspection Guide

S. 19. XN Series Influence of Interfering Material on Hematology Parameters, Document Number: 1028-MKT

T. 20. Soldin, SJ, Brugnara C., Wong EC. *Pediatric Reference Intervals*, AACC Press

Trademarks

Attachments

- XN Analyzer Area IPU Display.png
- XN Manual sampler.png
- XN QC Read Assay File.png
- XN-1000 Sampler Analysis.png

Approval Signatures

Step Description	Approver	Date
Technical Specialists	Colleen Turtenwald: Technical Specialist	Pending
Technical Specialists	Carolyn Webb: Heme Technical Specialist	03/2025
Policy Owner	Carolyn Webb: Heme Technical Specialist	03/2025

Applicability

Community Physician

Standards

No standards are associated with this document