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Owner	Carolyn Webb: Heme Technical Specialist
Area	Hematology
Applicability	Community Physician

XN550 Operation and Maintenance

SCOPE

LABORATORY:

Tosa Health Center

North Hills Health Center

Harbor Town Health Center

INSTRUMENT(S):

XN-550 (part of the XN-L series of Sysmex analyzers)

TEST ORDER, MNEMONIC:

CBC, CBCD, H&H, HGB, HCT, PLT, CPLT

DAYS OF PERFORMANCE:

Each day of laboratory operation

TURNAROUND TIME (TAT) EXPECTATIONS:

Routine: 4 hours

Stat: 30 minutes

CLINICAL UTILITY

The Sysmex XN-550 is used in screening patient populations found in clinical laboratories. This instrument enables quantitative, identification, and existence ratio analysis of tangible components of blood, (red blood cells, white blood cells, platelets, and other cells).

TESTING PRINCIPLE

The XN-550 performs hematology analyses based on the hydrodynamically focused impedance measurement, the flow cytometry method (using a semiconductor laser) and the SLS-hemoglobin method.

The analyzer counts and sizes red blood cells (RBC) and platelets (PLT) using hydrodynamic impedance counting (sheath flow DC method). At the same time the hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood via the RBC pulse height detection method.

Flow Cytometry is used to analyze physiological and chemical characteristics of cells and other biological particles. Flow cytometry is a method used to analyze those cells and particles as they pass through extremely small flow cells.

Directly Measured Parameters: WBC, RBC, HGB, HCT, RDW-SD, PLT-I, NEUT%, LYMPH%, MONO%, EOS%, BASO%, IG%, WBC-BF*, RBC-BF*, TC-BF*, BF-PMN%*, BF-MN%*, RETIC%*, RET-HE*, IRF%*. Note: * items are not used at Froedtert laboratories.

Calculated Parameters: MCV, MCH, MCHC, RDW-CV, MPV, NEUT#, LYMPH#, MONO#, EOS#, BASO#, IG#.

SPECIMEN

PREFERRED:

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

ACCEPTABLE:

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 acceptable volume is 1 mL for 12x75 mm tube,
2. Microtainer tubes are also acceptable. 250 uL is minimum acceptable volume for microtainer tube.
3. Do NOT use the predilute mode on the XN550 analyzer to try to salvage samples with volumes less than 1mL in 12x75 mm tube or less than 25 uL in a microtainer tube.

NOTE: The minimum volumes stated are those required for appropriate sampling by the analyzer. 25 µL of sample is aspirated regardless of which tube type or analysis mode is used.

STABILITY:

TEMPERATURE:	TIME:
AMBIENT	8 hours
REFRIGERATED	24 hours
FROZEN	unacceptable

Unacceptable specimens

Specimens are rejected for the following reasons:

- Fibrin or clots
  - XN-L series analyzers provide flagging to identify samples with platelet clusters or fibrin. Checking for fibrin/cots is only required when flags are present.
- Hemolyzed specimens
  - 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:

- Lipemia,
- Icterus
- 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 *(See also "Frequently Used Consumables" document on Sysmex CRC.)*

A. Test tubes

B. CELLCLEAN® AUTO

C. Sysmex reagents

D. Commercial Quality Controls; XN CHECK™ (recommended) or XN-L CHECK™ (acceptable)

REAGENTS:

A. General Information

1. Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-550 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.**

B. **Diluents**

1. CELLPACK DCL: Whole blood diluent for use in hematology analyzers.
2. 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 use.
    c. CELLPACK DCL is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace container.
3. CELLPACK DCL Stability

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

b. Opened, stable for 60 Days.

4. CELLPACK DCL Hazard Risk: non-hazardous.

C. **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.

    a. SULFOLYSER Storage

        i. Store at 1^{O}-30^{O}C away from direct sunlight.

        ii. If frozen, thaw and mix thoroughly before using.

        iii. Allow the container to equilibrate to environmental temperature (15-35^{O}C) prior to use.

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

    b. SULFOLYSER Stability

        i. Unopened, stable until expiration date printed on the container.

        ii. Opened, stable for 60 Days.

    c. SULFOLYSER Hazard Risk non-hazardous

2. 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, eosinophils and basophils are analyzed.

    a. Lysercell WDF Storage

        i. Store at 2^{O}-35^{O}C away from direct sunlight.

        ii. Use at an environmental temperature (15-35^{O})

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

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

    b. Lysercell WDF Stability

        i. Unopened, stable until expiration date printed on the container.

        ii. Opened, 1L stable for 60 days, 2 x 4L stable for 90 days.

    c. Lysercell WDF Hazard Risk non-hazardous

D. **Staining Reagents**

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

a. Fluorocell WDF Storage

i. Store at 2°-35°C in a dark place.

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

b. Fluorocell WDF Stability

i. Unopened, stable until expiration date printed on the container.

ii. Opened, stable for 90 Days.

c. Fluorocell WDF Hazard Risk Refer to the SDS.

i. Hazard identification

a. Harmful if swallowed

b. Harmful if inhaled

c. May cause damage to organs

ii. Hazard Precautions

a. Wash face, hands and any exposed skin thoroughly after handling

b. Do not eat, drink or smoke when using this product

c. Use only in a well-ventilated area

d. Do not breath vapours

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

E. 1. **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 on XN-L Series automated hematology analyzers.

i. 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.

ii. CELLCLEAN AUTO Stability

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

iii. CELLCLEAN AUTO Hazard Risk Refer to the SDS

a. CELLCLEAN AUTO is corrosive and may cause burns to skin.

REAGENT STABILITY SUMMARY:

XN-L REAGENTS	OPEN EXPIRATION
CELLPACK™ DCL	60 Days (20L/10L)
SULFOLYSER™	60 Days (2 x 1.5L)
Lysercell™ WDF	90 Days (2 x 4L)
Fluorocell™ WDF	90 Days (2 x 42mL)
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-L-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-550 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:

Run three levels of controls each day before testing patient samples. (A minimum of 2 levels of controls must be run at least once every 24-hours.)

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-550 analyzers**
    1. **XN CHECK or XN-L CHECK**
        a. Manufactured by Streck, available as a tri-level package.
        b. Whole blood commercial control used to monitor performance of all XN-550 analyzers.

c. Formulation

i. XN CHECK Consists of human red and white blood cells with a platelet component suspended in fluid medium. XN-L CHECK consists of human and/or animal 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 and XN-L CHECK is stable until the expiration date printed on the unopened vial.

ii. Open vial stability is 7 days for XN CHECK and15 days for XN-L 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/XN-L 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, XN-L 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, XN-L 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.

PREPARATION:

A. Remove vials from the refrigerator and allow them to come to room temperature (18-25^{O}C), for approximately 15-30 minutes.

B. Mix vials according to the package insert accompanying the product until the cell button in the bottom of the vial is completely suspended.

C. Perform a close visual inspection of each vial confirming the cell button is completely removed from the bottom of the vial and cellular elements are uniformly suspended with no aggregates.

QC ANALYSIS

XN Check / XN-L CHECK QC Analysis

A. Confirm the analyzer is in a Ready state.
B. Touch [Mode] on the control Menu.
C. Touch the Analysis Mode. Select Whole Blood.
D. Touch OK.
E. Open sampler adaptor and place tubes in sample adapter.
F. Touch Sampler, then touch screen to indicate Starting Tube Position.
G. Touch OK.
H. Close Sampler adapter holder.
I. Press the start switch.
J. Results are automatically transmitted through SNCS to BCQM and *Insight*.
K. Check the analysis results in BCQM.

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. **North Hills ID:** 81654@bcqm.com
       Password: bcqm1234
    2. **Tosa ID:** 81539@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.

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

1. P = Last 2 different levels of QC passed
2. F = QC failed
3. B = Background counts pass
4. X = Background counts failed
5. ? = Run QC
6. L = XNBF QC passed
7. D = XNBF QC failed
8. S = service event
9. Calibration (EBC)

D. ***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.

1. 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.
2. 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

Manual Registration of new lot of QC material

A. Select [QC File] icon.
B. Select a QC file that does not have a lot registered. Choose empty spaces that allows three controls to be registered in sequence.
C. Select [Register].
D. Select [Read Assay file].
E. Select the correct QC product, lot number, and level.
F. Select [Ok].
G. Verify the QC lot number, level and expiration date matches the QC vials received by the lab.
H. Repeat for each level of XN-L CHECK to be registered.

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 monthly by key operator, technical specialist, supervisor, or manager:
    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 Assitance 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

XN-550 Reagent Replacement

A. When the replacement of reagent is required, an error message appears. Promptly acknowledge the error message by clicking execute to enter the reagent replace dialog box and proceed to replace the indicated reagent. Verify that “CAPS LOCK is off.

1. CAUTION:
    a. Do not use the reagent outside of the written intended use, or not according to the written directions for use.

b. When replacing this reagent, do not refill and use the same container.
c. Handle the reagent with care to prevent air bubbles from foaming.
d. Do not use expired reagents.
e. 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.
f. 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.
g. Before use, please read the safety data sheet carefully.

B. Replacing a new diluent / hemolytic agent
1. Touch the name of the reagent to be replaced.
2. Place a check-mark next to 'Replace the reagent,' then place the cursor in the reagent code text box.
3. Using the hand-held reader, scan the reagent code on the new reagent container. **NOTE:** Scan Reagent Code 2 when available on the reagent container.
4. Remove the cap from the expired/empty container and carefully remove the spout.
5. Pull out the dispensing, set straight up.
6. Insert the dispensing set straight into the new reagent container and close the cap.
7. Select [Execute]
a. Reagent replacement starts. When complete, the dialog box closes automatically.

C. Replacing Dye
1. Display the [Reagent Replacement] dialog box.
2. Prepare the new reagent cartridge.
a. Confirm the reagent has not expired.
3. Pull out the dye holder.
4. Slowly remove the dye cover, taking care that dye does not drip.
5. Remove the entire dye holder.
a. When the dye holder is removed, a Help dialog box appears in the IPU screen.
6. Remove the old reagent cartridge from its holder.
7. Install the new reagent cartridge into the holder.
a. Make sure the color of the label on the new reagent cartridge matches the

color of the dye cover and install. Analyzer will beep as confirmation of new reagent installation.

b. If the wrong reagent is installed, the analyzer beeps repeatedly and the Help dialog box appears in the IPU screen.

8. Place the dye cover.
    a. Place into dye holder.
    b. The ID of the new reagent is read automatically and the information is registered.
9. Close the dye holder.
    a. Reagent replacement starts.
    b. When complete, the reagent replacement window closes automatically.
10. Reagent Replacement Documentation: 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.

DAILY MAINTENANCE

A. XN-550 Shutdown – performed at end of each day
    1. Confirm analyzer and sample unit are at ready.
    2. Open Sample Cover (manual unit).
    3. If any tubes remain in holder, remove.
    4. Touch [Menu] on Toolbar.
    5. Touch [Shutdown]. Touch [OK].
        a. XN-L on-board maintenance history will auto-populate Shutdown.
        b. IPU will automatically shut off at the conclusion.

WEEKLY MAINTENANCE

A. XN-550 Routine Cleaning – performed weekly.
CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-L Series Troubleshooting Manual for detailed, illustrated procedures.
    1. Confirm analyzers, sampler unit are at ready.
    2. Touch the [Maintenance] Icon in the Menu screen.
    3. Touch [Rinse Instrument].
    4. Touch [Routine Cleaning].
        a. Open Sampler Cover (manual unit) and place CELLCLEAN AUTO in tube holder.
        b. Press start switch.

c. XN-550 on-board maintenance history will auto-populate Routine Cleaning.
CAUTION: Use 1 vial of CELLCLEAN AUTO for each instrument. Do not reuse CELLCLEAN AUTO that has previously been used. During Shutdown, other sample tubes are not accepted.

5. Maintenance performed on the XN-550 will be automatically tracked in the analyzer's maintenance history.

AS NEEDED MAINTENANCE

XN-550 analyzer or BCQM will prompt operator if 'as needed' maintenance is required. Refer to attached XN-550 Troubleshooting Manual for ‘as needed’ maintenance. All maintenance performed on the XN-550 will be automatically tracked in the analyzer's maintenance history.

PROCEDURE

START-UP PROCEDURE

A. Checks prior to turning:
   1. Visual inspections of analyzer / system / reagents
   2. If applicable, verify waste container is empty.
   3. Verify network / host connections are properly working.
   4. Verify sufficient reagent supply is nearby.

B. Turning ON the entire system
   1. Verify that all power switches for the device are in the ON position.
   2. Press the **Green** power button on the front of XN-L to power ON the entire System.

C. Log on to the XN-550 IPU
   1. When the logon dialog box appears, enter username and password.

D. Analyzers self-checks
   1. XN-550: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times).

E. Tech performs QC.

XN-L Acceptable Background Counts	
Parameters	**Acceptable Limit**
WBC	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

PATIENT SAMPLE PROCESSING

A. System Analysis (sampler analysis)

1. Make sure the sampler cover (front) and sampler cover (manual unit) are closed.
2. Make sure the button on the right edge of the control menu is set as sampler. When the mode is set to manual, press the mode switch.
3. Make sure that either the left or right sampler adapter holder is in a state to be pulled out.
    a. 1. A sampler adapter holder can be pulled out when the sampler adapter status indicator LED is solid green or OFF.
4. Pull out the sampler adapter holder that you want to use.
    a. Remove the sampler adapter.
    b. Mix the sample.
    c. Place the sample tube in the sampler adapter.
    d. Touch Sampler on the right edge of the control menu.
    e. Touch an item to set the condition.
    f. Touch [OK].
    g. Place the sampler adapter in the sampler adapter holder selected in the sampler settings box.
5. Push in the sampler adapter holder.
6. Press the sampler analysis start/stop switch.
7. Caresphere rules will determine repeat or reflex testing.
8. Rack will run in reverse to perform repeat or reflex testing.
9. Remove the rack from the left sampler pool when analysis in completed.
10. Make smear if indicated.

B. Manual Analysis

1. Check the status of the analyzer. Confirm the analyzer is ready.
2. Make sure the button on right side of control menu is Manual. When it's set to Sampler, touch [Mode] in the control menu.
3. Select the Change Analysis Mode button on the control menu.
4. Select analysis mode.
    a. [Whole blood] is selected when whole blood is being analyzed
    b. [Low WBC] Select this to perform low WBC analysis on whole Blood
5. Select [OK]

6. Select Manual Analysis button on the control menu
7. Input sample ID or use handheld barcode reader to scan sample ID.
    a. Patient information- Touch Input to enter patient ID.
    b. Query to Host-Specify whether or not the host is queried for the analysis order.
    c. Aspiration Sensor- Specify whether or not the aspiration sensor is used.
    d. Cap Open- Select this checkbox to perform micro sample analysis (analysis with the sample tube cap open.)
    e. Raised Bottom Tube- Assure appropriate adaptor in use – *See Instructions for Use Manual*.
    f. Dispense- Used to prepare diluted blood. Touch to start dispensing CELLPACK DCL. For the dispensing procedure, see the following: (section 4.8 Preparing diluted blood with the diluent dispensing function in the XN-L Series Basic Operation Manual)
8. Select [OK]
9. Open the Sampler cover (manual unit).
10. Properly mix the specimen (invert 10 times) and place in the tube holder.
    a. If running micro sample, remove the cap using caution to avoid splattering.
11. Press the start switch on the analyzer.
    a. The tube holder will slide in and the sample will be aspirated
    b. When the analysis is complete, the tube holder slides out
12. Remove the sample, repeat steps for additional samples.
13. Review results in Caresphere to determine whether repeat or reflex testing is required. Rerun sample if required. Make smear if required.

RESULT INTERPRETATION

REPORTABLE RANGE:

- **ANALYTICAL REPORTABLE RANGE:** XN-L Series Manufacturer Stated Reportable Range
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Parameter	Range	Units
WBC	0.04-440.0	$x10^3/\mu L$
RBC	0.02-8.60	$x10^6/\mu L$
HGB	0.1-26.0	g/dL
HCT	0.2-74.5	%
PLT	2-5000	$x10^3/\mu L$

- **CLINICAL REPORTABLE RANGE:**
    - Clinical reportable range is the same as analytical reportable range for the XN-550 analyzer.
    - Do not perform dilutions on the XN550 analyzer. Send any specimen that requires dilution to WDL.

DILUTIONS:

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

FOLLOW UP ACTIONS

A. Flagging and Action Messages
    1. Abnormal samples on the XN-L 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-L Series Automated Hematology Systems Flagging Interpretation Guide for additional information on flagging.

B. 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 both smears do not match the analyzer count, do not release results to patient chart. Send the specimen to WDL or hub lab to perform fluorescent platelet count.
    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 Handling Abnormal Hematology Samples Procedure

C. If Caresphere is unavailable, all suspect messages, definitive messages, and * results need follow up prior to reporting results. Refer to Hematolgy Downtime Procedure for details.
    1. Refer to attached XN-L Series Flagging guide for additional guidance

EXPECTED RESULTS:

- See Hematology Reference Ranges and Critical Values Procedures for REFERENCE INTERVALS and CRITICAL VALUES

CALCULATED DATA - APPLICABLE FORMULAS:

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. Laboratories with XN550 analyzers should place specimens on analyzer within 4 hours of collection. Premixing is not needed for these samples.

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

REFERENCES

A. Sysmex XN-L Series Basic Operation (North American Edition), Sysmex Corporation, Kobe, Japan.

B. Sysmex XN-L Series General Information (North American Edition), Sysmex Corporation, Kobe, Japan.

C. Sysmex XN-L Series Troubleshooting (North American Edition), Sysmex Corporation, Kobe, Japan.

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

E. Sysmex Reagents of America Inc., Mundelein, IL. XN CAL, Hematology Calibrators: Calibrators for Sysmex Hematology XN-L Series Analyzers, package insert.

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

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

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

I. Sysmex America Inc., Lincolnshire, IL. XN-L Applications Manual.

J. Sysmex XN-L Series Automated Hematology Systems Flagging Interpretation Guide.

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

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

Attachments

XN-550 TROUBLESHOOTING MANUAL.pdf

XN-L Series Flagging Guide.pdf

Approval Signatures

Step Description	Approver	Date

Applicability

Community Physician

Standards

No standards are associated with this document