Sysmex XN Quality Control

Policy

Quality control is performed to monitor an analyzer's performance over time. XN CHECK and XN CHECK BF are used to monitor the performance of the XN analyzer. Quality control should be run in accordance to licensing agency regulations and laboratory policy. It should be noted that for troubleshooting purposes, additional control runs may be necessary.

To QC the SP-10, examine a stained smear from the routine workload for smear and stain quality on a daily basis.

Document results on appropriate log.

Safety

All specimens, reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing scheduled maintenance. Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01.

Reagents

Control Material for XN analyzers:

1. **XN CHECK**
    a. Manufactured by Streck, available as a tri-level package.
    b. Whole blood commercial control used to monitor performance of the XN analyzers.
    c. Storage: Store vials at 2-8^{o}C
    d. 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.

2. **XN CHECK BF (for body fluid)**
    a. Manufactured by Streck, available as a bi-level package.
    b. Body Fluid commercial control used to monitor performance of the XN analyzer body fluid analysis mode.
    c. Storage: Store vials at 2-8^{o}C
    d. Stability:
        1. Unopened and properly stored, XN CHECK BF is stable until the expiration date printed on the unopened vial.
        2. Open vial stability is 30 days when promptly refrigerated after each use.
        3. Record the date on each vial upon opening or cap piercing.

Reagents, continued

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

3. **SP-10 Quality Control**
   Daily, examine a stained smear from the routine workload for smear and stain quality. Document results on appropriate log.

Frequency of QC run & review

Frequency of Control use and review:

XN CHECK control levels: **ALL 3 levels** will be run daily on **ALL** (1st, 2nd & 3rd) shifts and **ALL** XNs.

XN CHECK BF control levels: **All 2 levels** will be run on **ALL** (1st, 2nd & 3rd) shifts in the Manual BF mode. **Body Fluid analysis will be done primarily on XN 3**. And XN 2 will be the backup.

SP-10 QC slide will be evaluated daily on the 1st shift.

QC run time:

AM shift – 0830 +/- 30 minutes (0800 to 0900)
PM shift – 1630 +/- 30 minutes (1600 to 1700)
Night shift – 0030 +/- 30 minutes (0000 to 0100)

Note: Since the XN only has one sample pathway, i.e. it only has one needle for aspiration, it does not matter whether it is done in AUTO or MANUAL mode.

Procedure

Remove vials from refrigerator and allow them to come to room temperature (18-25°C), for approximately 15 minutes.

Mix vials by gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended.

XN Check QC Sample Processing:

Auto Mode	
Step	**Action**
1	Make sure the analyzer and the sampler are in **READY** state.
2	Check that tube holder has retracted into the analyzer, press mode button if necessary.
3	Place QC in **RED** labelled rack in the feeder. Feeder will auto-start and send QC material to each XN module.
4	When analysis is done, results will be displayed in the IPU.
5	Results will be plotted on the L-J Chart as well as the Radar Chart for review.
6	Review QC results for acceptability.
7	Repeat if necessary and log in corrective action log.

Manual Mode	
Step	**Action**
1	Check the Status indicator LED on the analyzer to confirm analyzer is in **READY** state.
2	Press the mode switch to eject the tube holder.
3	Properly mix the QC sample and place in the tube holder.
4	Press the start switch on the analyzer. • The tube holder will slide in and the sample will be aspirated • When the analysis is complete, the tube holder slides out
5	Remove the QC sample, repeat steps for next QC sample.
6	Review QC results for acceptability.
7	Repeat if necessary and log in corrective action log.

XN CHECK BF QC Sample Processing:

Manual Mode Only	
Step	**Action**
1	Check the Status indicator LED on the analyzer to confirm analyzer is in **READY** state.
2	Press the mode switch to eject the tube holder.
3	Select the **Change Analysis Mode** button on the control menu.
4	Select **[Body Fluid]**. **Note**: The analyzer will automatically perform a background check up to three times.
5	Select **[OK]**
6	Properly mix the QC sample and place in tube holder.
7	Press the start switch on the analyzer. • The tube holder will slide in and the sample will be aspirated • When the analysis is complete, the tube holder slides out
11	Remove the QC sample.
12	Perform background check prior to running additional QC samples by selecting **[Auto Rinse]** from the analyzer menu button.
13	Review QC results for acceptability.
14	Repeat if necessary and log in corrective action log.
15	Return analyzer to Whole Blood mode prior to running whole blood samples by pressing the mode switch button.

For Manual Mode Only:
If vial barcode is unreadable, select the analyzer menu button on the control menu, then:

1. Select **[QC Analysis]**
2. From the list of QC files, select the file to be analyzed. Judgment dialog box will open automatically.
3. Place thoroughly mixed vial in tube holder, press start switch.

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

SP-10 Daily QC Slide Review:

Step	Action
1	**Review the blood smears macroscopically for acceptability:** 1. Smears are sufficient length (greater than half the length of the unfrosted portion of the slide). 2. The feathered edge becomes gradually thinner without streaks, holes, or tails. 3. Even, consistent staining of blood smear.
2	**Review the blood smears microscopically for acceptability:** 1. Relatively even distribution of cellular elements. 2. Acceptable morphology within the working area. 3. None or very little artifact of the cell morphology, (e. g., “punched-out” RBC’s, smashed WBC’s). 4. None, or very little stain precipitate or debris. 5. The staining is consistent and imparts the characteristic cytoplasmic color differences and distinct nuclear chromatic patterns of the whole spectrum of blood cells. Acceptable stains will display the following characteristics: a. RBC’s should be pink to orange. There should be good differentiation between normochromic, hypochromic, and polychromatic cells. b. Lymphocytes will display dark purple nuclei with varying shades of blue cytoplasm. c. Neutrophils will display dark purple nuclei, with light pink cytoplasm and lilac granules. d. Monocytes will show lighter purple nuclei. The cytoplasm of the monocytes will be gray-blue with reddish granules. e. Eosinophils show bright orange granules in the cytoplasm. f. Basophils display dark blue granules in the cytoplasm. g. Platelets will be violet to purple. If smear quality is unsatisfactory, clean, or if necessary, replace the spreader glass. If still unable to obtain an acceptable smear, refer to the SP-Series Implementation Manual troubleshooting section. If the troubleshooting steps do not resolve the problem, notify the supervisor / key operator when available or call the Sysmex Technical Assistance Center (TAC) 1-888-879-7639. Document all corrective action.

Evaluate QC

Westgard rules are used to evaluate the acceptability of a set of observed control data. These rules are based on the theory that repeated assays of a control will fall within a random yet predictable "scatter" about a pre-defined mean.

QC Rules & Definitions:

1. One 3S rule = One control exceeds X ± 3 SD limit, **DO NOT REPORT PATIENT RESULTS** until corrective action is performed.

2. Two 2S rule = (Across run) Same control exceeded the same -2 SD or +2 SD limit, **DO NOT REPORT PATIENT RESULTS** until corrective action is performed.

3. Two 2S rule = (Within run) Both controls exceeded the same -2 SD or +2 SD limit, **DO NOT REPORT PATIENT RESULTS** until corrective action is performed.

4. Four 1S rule = Four consecutive values outside the same 1S, report patient results. Monitor future control runs for rules violations

5. Ten consecutive values on one side of mean report patient results. Monitor future control runs for rules violations.

Step	Action
1	Review QC results for acceptability by clicking on the QC file icon. This will allow you to view the files in: b. QC File screen 1. Allows for review of the latest QC results in Radar Chart format for the QC file that is selected in the list. 2. Any point exceeding the upper or lower limit is marked with a red “X”. b. QC Chart screen 1. Allows for review of detailed graph data of all QC runs for selected file. 2. Analysis data is plotted cumulatively and displayed in the chart area as a line graph. 3. Any point exceeding the upper or lower limit is marked with a red “X”. 4. User must scroll up and down through the chart to view all parameters for each run.
2	Controls are flagged in red if the values fall outside of 2 SD. When this occurs, the CLS needs to check the QC chart for the corresponding shift and classify rules broken.
3	When a rule violation occurs, document in the ACTION LOG and perform appropriate remedial action.

QC Management

Refer to: HEM.02-0020 Processing QUALITY CONTROL for IQAP (***Insight***) for more detailed information.

Follow steps below to manage QC:

Step	Action
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: 1. Statistical computations (SD, Mean, CV) 2. Variable target computation 3. Number of data points = n
2	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.
3	A comment may be added to the QC data selected by the cursor: 1. Select **[Input Any Comment]** to input a free text comment. 2. Select **[Fixed Comments]** to use a comment from a list of preset comments in the QC settings menu. 3. Select **[OK]** 4. A comment bubble will be displayed when a comment exists for a QC run. 5. The comment will be visible in the comment display area when the cursor is placed on the QC run

Printing & Storage of QC Data:

Step	Action
1	Select QC Files Icon and highlight file to output.
2	Select QC Chart Icon.
3	Set Range of points to output by clicking **[Range]** and capturing the points with the cursors.
4	Select **[output]** to print the selected chart to either GP or LP.
5	Select **[file]** to save the data to removable media.

Reference

1. Sysmex XN-9000 *Instructions for Use* (North American Edition), Sysmex Corporation, Kobe, Japan.
2. Sysmex XN series *Administrator's Guide* (North American Edition), Sysmex Corporation, Kobe, Japan
3. Clinical and Laboratory Standards Institute (CLSI). Laboratory Documents: Development and Control; Approved Guideline; Fifth Edition. (GP2-A5, 2006).
4. Sysmex America Inc., Lincolnshire, IL. XN CHECK Hematology Control for Sysmex XN-Series Analyzers package insert.
5. Stewart, Charles and Koepke, John. *Basic Quality Assurance Practices for Clinical Laboratories*, Van Nostrand Reinhold, 1989, p 189.

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Implemented
New	Procedure for new XN instruments.	Julius Salomon, 7/1/17			