Sysmex XN Quality Control

Policy

Quality control is performed to monitor an analyzer's performance over time. XN CHECK is 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-50, examine a stained smear from the routine workload for smear and stain quality on a daily basis.

QC results for the XN and Cellavision should be reviewed and accepted/ approved by CLS before reporting patient results.

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.

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.

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

2. **SP-50 Stain Quality Control**

   Daily, examine a stained smear from the routine workload for smear and stain quality. This is incorporated in the daily Cellavision QC.

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Frequency of QC run & review

Frequency of Control use and review:

1. XN CHECK control levels: **ALL 3 levels** will be performed daily. All levels of controls should be analyzed at least once in every eight-hour shift for **both** XNs.
2. SP-50 QC slide will be evaluated daily on the Cellavision.

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^{o}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.

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SP-50 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. RBCs 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.

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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: **a. 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**.**

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3	When a rule violation occurs, document in the ACTION LOG and perform appropriate remedial action.

QC Management

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.

Processing QUALITY CONTROL for IQAP (*Insight*)

Quality control data for the Sysmex XN Check Controls are uploaded automatically to the Sysmex Insight Quality Assessment Program on the Sysmex website daily through SNCS connection. The data is used for evaluation and comparison with other XN analyzers. The Interlaboratory Quality Assurance Program (IQAP) is a service provided by Sysmex Corporation. The IQAP report provides interlaboratory comparison indicating precision and accuracy relative to peer data.

The laboratory maintains an SNCS™ connection, the QC results are transmitted automatically to ***Insight*** after each run. There is no need to batch upload the data to ***Insight***.

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Processing QUALITY CONTROL for IQAP (*Insight*) continued

Uploading QC data can also be done monthly/daily by the Hematology manager or a CLS with advance operator access if SNCS connection is not available.

Follow steps below to upload data manually:

Step	Action
1	Insert flash drive into USB port on the IPU's hard drive.
2	Select the QC file you want to output, click **[File]**, **[Output in Sysmex *Insight*]**. Save the file to the flash drive.
3	Repeat for each file needing ***Insight*** submission.
4	Properly eject the flash drive from the IPU.
5	At a networked PC, establish connection with the ***Insight*** program via www.sysmex.com/us and submit the data.

REVIEWING the IQAP REPORT

The Hematology supervisor reviews the IQAP report for accuracy and precision, investigates possibility of system error and documents results of investigation on the IQAP report.

Interpreting the Period Report flags:

W (Warning) limit flag. SDI values for the following parameters* will flag if outside of the established SDI range. You will see the flag in the Notes column of the report. This indicates that the analyzer should be monitored.

- Flagging at ± 2 SDI range*: RBC, HGB, HCT, MCV, PLT, WBC, and RET
- Flagging at ± 2.5 SDI range*: MCH, MCHC, RDW, NEUT, LYMPH, MONO, EO, BASO, NRBC, IRF, MPV, IG, RET-He, and IPF

If a flag persists for more than two reporting periods, the bias should be investigated.

P (Positive Bias) or N (Negative Bias) flag. SDI values outside a ±3 SDI range will be flagged in the Notes column of the report. These flags indicate a possible statistical bias, and a corrective action is recommended.

Accuracy
The SDI value represents the number of SDs by which the analyzers mean value for a parameter differs from the peer group's mean.

SDI= (Your Mean – Group Mean)/Group SD

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REVIEWING the IQAP REPORT, continued

Evaluating your analyzer's performance:

The following tips are provided as a guide to assist you in evaluating your analyzer's performance using Insight *Reports.*

1. "Rule of Three" When all three control levels on a parameter is biased in the same direction and same general magnitude, a systematic inaccuracy or imprecision is more likely to have occurred.

2. "Rule of One" When only one level is greater than ± 3 SDI, and the others are within ± 3 SDI. This could be due to statistically normal distribution. This is acceptable if the error involved is not clinically significant.

If a single level persists in being biased across reports and different lots of control, it may indicate a non-linear detector response that needs attention.

3. Use Relationships to Find Root Cause. SDI graphs can be used to identify patterns between related parameters. For example, an elevated HCT may result in an increased MCV and RDW-SD. In this case, troubleshooting should focus on correcting HCT inaccuracy as this change should normalize all the other affected parameters.

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REVIEWING the IQAP REPORT, continued

IQAP Checklist:

Situation	Action
Your data agrees with that of other participating labs: no flags	No action necessary.
Your SDI for one or more parameters/levels should be reviewed	Your accuracy needs to be reviewed. • Verify that the data on the report matches the data you submitted and that your data was submitted correctly. • Check for a pattern by comparing the data with other levels of the same parameter on the report. • Check for similar patterns in both previous and current lots of control.
Your CV for one of more parameters/levels should be reviewed.	Your precision needs to be reviewed. • Verify that the data on the report matches your records and that you submitted the data correctly. • Review maintenance procedures. • Review handling techniques of the cell control product.
Both SDI and CV for one or more parameters/levels should be reviewed.	First resolve the precision problem, then troubleshoot the accuracy problem. Follow the steps listed above.

Reference

1. Sysmex XN-3100 *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.