**HEM.SYSMEX.9.0 QUALITY CONTROL MANAGEMENT ON SYSMEX XS/XT/XE**

**PRINCIPLE**

Quality Control is a way to validate proper instrument function prior to reporting patient results. Controls should verify assay performance at relevant decision points. Quality control specimens should be tested in the same manner and by the same personnel as patient samples. Quality control management on the Sysmex XS/XT/XE analyzers includes entry of new QC lot data, recording and storage of QC data, and the Quality Assurance Program (QAP).

**OWNERS**

Manager, St. Vincent Anderson Hospital Laboratory

**RELATED DOCUMENTS**

HEM.SYSMEX.1.0 Complete Blood Count Using the Sysmex-XT Analyzers

HEM.SYSMEX.2.0 Complete Blood Count Using the Sysmex XE-5000 or XE-2100

HEM.SYSMEX.5.0 Complete Blood Count Using the Sysmex XS-1000i or XS-1000

**REAGENTS**

Please refer to the reagent section of: HEM.SYSMEX.1.0, HEM.SYSMEX.2.0, and HEM.SYSMEX.5.0

**PROCEDURE**

1. Frequency of controls
2. Two (2) levels of controls must be run during each 8 hour shift.
3. If a CLOSED and OPEN mode are both available and the CLOSED mode is utilized routinely, at least 1 level of control should be run in the OPEN mode once a day.
4. If the XS-1000i/XS1000 is utilized as the backup instrument only, all 3 levels of QC are performed each shift of use.
5. Entering Lot Information for a New Lot of Controls
6. XT and XE analyzers (Login as “ADMIN”)
7. In the QC program, click on the **Control** tab and select the Lot, Level, and Mode for the specified QC file.
8. Click **Lot No**. A box displays a window for lot information.
9. Manually input the 8 digit lot number and expiration date of selected new control level. \*\*\*Date is in Year/Month/Day order\*\*\*
10. Click **[OK]** to save new lot information. Verify new lot information is correct.
11. Lot number and date may be edited while in NEW file only.
12. If data exists in the NEW lot file, perform the “**Change Lot**” command.

**CAUTION**: Current Lot is deleted and New Lot moves to Current. Print Current L-J Charts to GP and QC Data to LP and Submit QAP data to ***Insight*** before proceeding with Change Lot.

* 1. In the QC program, click on the Control tab and select the Lot, Level, and Mode for the specified QC file.
  2. Click **[CHANGE LOT]**
  3. A warning message is displayed “Save QC Data before changing lot?”
  4. Select **[Yes]** to select the pathway to save QC information. Enter file name, then select **[Save]**. Select **[No]** if you do not want to save QC.
  5. Current QC Data is deleted and is replaced by the New Lot.

1. XS analyzers (Login as “ADMIN”)
2. Click **[QC Files]** or press **[F5]**
3. Click on file number (1-20)
4. Click **[Input]** or press **[F9]**. The QC dialog box displays.
5. Click on **[▼]** beside “Material” to select the control level.
6. Click in the field for “LOT NO.” Using the keyboard, enter the lot number from the vial or assay sheet.
7. Click on **[▼]** beside the “Exp. Date” to display the calendar. Click on the expiration date in the calendar to display it in the field.
8. Click **[OK]** to update the lot information.
9. Repeat the above steps to enter lot information for the other levels of control.

**NOTE**: L-J limit errors will occur when running the new lot of QC until the control values are auto-set.

1. Set Variable Target (used to establish lab’s running mean for control)

Do this each time a new lot of Quality Control information is entered.

1. XT and XE analyzers (Login as “ADMIN”)
2. In the QC program, click on the **Control** tab and select the lot, Level, and Mode for the specified QC file.
3. Click **[TARGET/LIMIT].**
4. First parameter is highlighted. Click first parameter and drag cursor to include all QC parameters are backlit in blue.
5. Click **[VARIABLE TARGET]** and **[OK].**
6. XS analyzer (Login as “ADMIN”)
7. Select the appropriate QC file.
8. Click **[Input].**
9. Click on RBC in the Target/Limit window and click and drag to include all parameters.
10. Click **[Variable Target].**
11. Click the “Target” check box to select.
12. Click **[OK]** on the “Input Lot Information” screen.
13. Repeat above steps for each level of control.
14. To Auto-Set Target Values (set mean value)

Parallel test new controls by analyzing the three levels of control whenever the current lot is run. Analyze New Lot of QC at least 10 times before auto setting target values

1. XT and XE analyzers (Login as “ADMIN”)
2. In the QC program (QC Icon), click on the **Control** tab and select the Lot, Level, and Mode for the specified QC file.
3. Click on **[CHANGE LOT]** to move the NEW lot data to the CURRENT lot file replacing any data that was present in the CURRENT lot file. Print or back up any CURRENT data **before** executing the Change Lot command. Skip this step if the data is already in the CURRENT file.
4. Select the range of QC data to be used for calculating targets by clicking and dragging the dark green line to the left or press **[CTRL]** and **[A]** to select all QC data points.
5. The Mean, SD, CV% for the selected range of QC data points will be displayed in the data column to the right of the QC chart.
6. Click **[TARGET/LIMIT].**
7. First parameter is highlighted. Click top of list of parameters and drag cursor to include all QC parameters.
8. Click **[AUTO SETTING].** Auto setting window is displayed.
9. Verify there is a check next to **TARGET** only. Do not check **LIMIT.** Click **[OK].** Target values should now be displayed in the TARGET column. The targets will be auto-set to the mean of the points in the QC file.
10. Click **[OK]** again to save the calculated target values.
11. Repeat steps a – I for each level of control.

k. Check that the new auto-set “target” falls within the assay range on the control

package insert. Check the correct assay range for your appropriate mode (open

vs. closed). If not within range, call Sysmex customer service for further

assistance.

1. XS analyzers
2. Login as “admin”
3. On the IPU, click **[QC Files]** or press **[F5].**
4. Double-click on the appropriate file number (1-6) to open the L-J chart.
5. Set the range of data for target calculation by clicking on the green cursor and dragging to the left to include all points to be used in calculation, or press **[Ctrl]** and **[A]** to select all data.
6. Click **[Input].**
7. Click on RBC in the Target/Limit window and click and drag to include all parameters.
8. Click **[Auto Setting].**
9. Click the “Target” check box to select. Click **[OK].**
10. The targets will be auto-set to the mean of the range of points selected in the QC file and will display in the Target/Limit window.
11. Click **[OK]** on the “Input Lot Information” screen.
12. Repeat above steps for each level of control.
13. Check that the new auto-set “target” falls within the assay range on the control package insert. Check the correct assay range for your appropriate mode (open vs. closed). If not within range, call Sysmex customer service for further assistance.
14. QC Analysis

For peer group comparison purposes (AP), run the control in the mode(s) most used for patient analysis – either Closed (Sampler) Mode or Manual Mode.

1. XT and XE analyzers (Login as “ADMIN”)
2. QC analysis in the **Closed (Sampler) Mode** with barcodes.
3. Place the room temperature, thoroughly mixed control vials in the rack with the barcode labels facing the analyzer.
4. On Main Unit, press **[SAMPLER]** and then **[START]** from the Select menu.
5. After the controls are analyzed, click on the “**QC**” icon on the IPU.
6. Click on the *e*-CHECK / Control tab to display the L-J charts.
7. Click on **[▼]** beside **Level** and select Level 1-3.
8. Click on **[▼]** beside **Mode** and select “Closed”.
9. Click on **[▼]** beside **Lot** and select “New” or “Current”.
10. Use the scroll bar on the right of the charts to view all parameter charts.
11. Verify that the mean of all parameters fall within the laboratory’s established limits or within the package insert assay range during the parallel testing phase. If the mean of a parameter falls outside of the range, contact the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX) to investigate possible control product failure.
12. QC analysis in the **Manual Mode**.
13. Press **[QC]** on Main Unit. If “QC” is not displayed in the function menu, press **[MORE]** to see more menu options.
14. Press **[EXEC. QC]**.
15. Select the file from the list number using **[▲]** or **[▼]**.
16. Press **[SELECT].**
17. Aspirate the room temperature, mixed control vial via the whole blood aspiration pipette.
18. Once results appear on the Main Unit screen, compare them to the laboratory’s established limits or to the package insert assay range during the parallel testing phase, using **[▲]** or **[▼]** to review all results.
19. On the Main Unit, press **[OK]** to accept the results. Press **[CANCEL]** to reject.
20. Follow steps c-g to analyze other levels of controls.
21. If parameter mean falls outside of the expected ranges, contact the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX) to investigate possible control product failure.
22. XS analyzers (Login as “ADMIN”)
23. QC analysis in the **Manual** mode.
24. Click **[Manual]** or press **[F2]**. The Manual Sample No. dialog box opens.
25. Enter the lot number using one of the following methods:
    1. Use the handheld barcode reader to scan the bar code from the vial.
    2. Use the keyboard to type the lot number.

**NOTE**: *“QC” must be upper case followed by a hyphen.*

* 1. Click the **[QC]** button on the Manual Sample No. dialog box.
  2. Click on the QC level to be analyzed. Click on **[OK]**.

1. Press the Open/Close switch to open the sample position.
2. Attach the appropriate tube adapter for the vial to be analyzed.
3. Place the well-mixed vial in the adapter and press the **“Start”** switch on the main unit.
4. The QC results display when analysis is complete. Results that are outside of acceptable limits display with red background. Click **[ACCEPT]** to accept the results, or **[CANCEL]** to reject.
5. Follow steps above to analyze other levels of controls.
6. QC analysis in the **Sampler** mode with **Barcodes.**
7. Place a Sysmex rack in the rack position of the sampler with the notch on the rack to the right.
8. Place the well-mixed control vials in positions 8, 9, and 10 of the Sysmex rack.
9. Attach the appropriate sample tube adapter.
10. Close the sampler cover.
11. Click **[Sampler]** or press **[F3].**
12. The sampler Sample No. dialog box displays. Click on the starting position for the rack and tube position in which the vials have been placed.
13. Press the sampler **Start** switch on the left side of the main unit.
14. A dialog box displays when analysis is complete.
15. Review QC
16. Radar Charts
17. On the IPU, click **[QC Files]** or press **[F5].**
18. Click on the file to be reviewed.
19. The Radar Chart displays beside the selected file.
20. Results of the most recent analysis display in blue. Date and time of analysis are displayed in the Analysis Date column.
21. Results outside of acceptable limits are displayed with a red “X” and the parameter name is displayed with a red background.
22. L-J Charts
23. On the IPU, click **[QC Files]** or press **[F5].**
24. Double click on the file to be reviewed. The Levy-Jennings chart will be displayed.
25. Results outside of acceptable limits are displayed with a red “X” on the L-J chart. The parameter name and the result value will be displayed with a red background.
26. Scroll through the screens to view all parameters by using the scroll bar on the right of the screen or press the down arrow.

Verify that the mean of all parameters fall within established limits or within the package assay range. Contact the Sysmex Technical Assistance Center to investigate any suspected control product failure.

1. Printing QC data
2. XT and XE analyzers
3. In the QC program, click on the Control tab and select the Lot, Level, and Mode for the specified QC file.
4. Click and drag the dark green line to the left to include specific range of QC data points or press **[CTRL]** and **[A]** to select all data points.
5. After selecting range, click **[REPORT], [Ledger (LP)]** to print QC data in line format.
6. After selecting range, click **[REPORT], [Report (GP)]** to print QC charts.
7. Repeat above steps to print each level and mode of QC data.
8. XS analyzers
   1. On the IPU, click **[QC Charts]** or press **[F5].**
   2. Double-click the appropriate file number (1-20) to open the L-J chart.
   3. Set the range of data to be printed by clicking on the green cursor and dragging to the left to include all points, or press **[Ctrl]** and **[A]** to select all data.
   4. Click **[Out]** or press **[F12].**
   5. Click on either “**Report (GP)**” for a graphic printout of the L-J chart of data, statistics, targets and limits or click on “**Report (LP)**” for line print of data, statistics, targets and limits.
9. ***Insight***™ Quality Assurance program (QAP)
   1. XT and XE analyzers

The key operator is responsible for uploading data to ***Insight*** on the Sysmex Web Site. Data must be submitted no later than 3 days after the due date on the Sysmex *e-*CHECK/*e*-CHECK(XE) assay sheet. For peer group comparison purposes (QAP), run the control in the mode most used for patient analysis. Each lot has 2 data submission dates, approximately every 40 days for the 84-day dated product. See assay sheets that are packaged with each lot of QC for submission dates.

* + 1. Save QAP Data

1. Sysmex ***Insight*** icon MUST be used for saving QC data for QAP.
2. Review data and if desired, edit (delete) control data prior to submission.
3. Click **[Sysmex *Insight*]** icon on IPU Main Menu.
4. Click drop-down options to select the following:
   1. **[MATERIAL]** to select control
   2. **[LEVEL]** to select Level 1, Level 2, or Level 3.
   3. **[ANALYSIS MODE]** to select Manual or Closed Mode.
   4. **[LOT]** to select Current or New lot
   5. **[INSTRUMENT ID]** to select analyzer.
   6. Verify QC Data Info in right column.
5. Insert USB Flash Drive into USB port and click **[SAVE].** **Save As** dialog box opens.
6. If a “*Please insert into Drive A*” message displays, click **[Cancel].**
7. Verify that the USB Flash drive name appears in **Save As** box. If not, click **[▼]** arrow and select drive (Removable disk) from list. *It may be necessary to remove the “A:\” in front of the file name in order to save the file on some analyzers.* Click **[Save].**
8. Repeat steps above for other levels or nodes if applicable.
9. With USB Flash drive still inserted, verify QC data was downloaded. Verify lot numbers and extension ending with “.ins”.
10. Remove USB Flash drive OR leave in if going to submit data from this computer.
11. Click **[CLOSE]** to exit Sysmex ***Insight*** function.

**NOTES**:

• Save each QC file separately.

• If saving both Closed and Manual Mode QC on same device, enter letter “C” or “M” respectively as first digit of file name. This prevents the second set of data from overwriting the first.

* + 1. Submit QAP Data to Sysmex

1. Go to www.sysmex.com/usa. Click Enter *Insight.*
2. Log on: **User name**: Enter your ***Insight*** customer email address

**Password:** Enter your ***Insight*** customer password. Click **Login**.

1. Click Submit QC Data.
2. Click **[▼]** arrow next to **Please select your Analyzer** and select your analyzer
3. To Select QC data file location, click **Browse**. Click **[▼]** next to **Look in** box.
4. Select ***Insight*** Data folder on desktop or Flash drive.
5. Click on **one** QC data file. Click **Open.** File name is displayed. Click **Submit Data File**.
6. Repeat steps above for other QC files.
7. Click **View QC Data Report** to view lot-to-date report.
8. Click **Log off**.

c. Submitting QAP Data without flash drive.

i. Select FILE, log off. Login in as user “admin.” There is no password.

ii. Click on the **QC icon**, then **Control tab**.

iii. Check each QC file for incomplete aspiration samples. Delete any

incomplete QC results by clicking on the incomplete data, then the

“**Delete Data**” icon.

iv. Click on **Menu** (at top of screen). “Deleted data will be completely

deleted.” Click **OK**.

v. Select **Sysmex *Insight*** icon. Select **Control level**. Click **SAVE.**

vi. “Please insert a disc into drive ‘A’.” Hit **CANCEL**.

vii. Select correct mode folder, *Insight* Data. **OPEN.**

viii. Click file name, same as lot number and level. **SAVE**. Do this for all three levels in the closed mode.

ix. Minimize screen.

x. Select ***Insight*** icon (not folder). Double click.

xi. Log-on with email and password.

xii. **QC Data – Submit QC** (left side)

xiii. Select correct analyzer.

xiv. Click “**Browse**” to find QC lot to be submitted. **OPEN**

xv. Click blue “**Submit Data File**” icon. Click **BROWSE.**

xvi. Do this until all three levels have been updated.

xvii. Click on “**View QC Data Report**” (bottom of screen) to ensure all values

were uploaded.

xviii. “Would you like to open file or save to computer?” Click **OPEN**

xix. Scroll to review all data to be submitted. Use the delete option to

remove any file that did not upload correctly.

xx. Log out of *Insight*.

xxi. Log out of “admin”

* 1. XS analyzers
     1. Reviewing QC data for ***Insight*** submission

1. Log into computer as “admin”. There is no password. Click “**OK**”.
2. Click on “**QC files**”.
3. Double click on each current lot/level of QC see Levy-Jennings plots.
4. Check each QC file for short aspirates or any other “gaps” of missing data. If any gaps are present, click so the green bar is in the middle of blue data points. Click “delete” to “connect” blue data points.
5. Log out of the computer.
   * 1. Submitting ***Insight*** data
6. Log on the XS as “admin”.
7. Highlight QC level 1 of current lot.
8. Click on ***Insight*** tab on tool bar at top of desk top.
9. A pop up box appears with the file name of QC (lot/level.) Click **SAVE**.
10. A popup appears “c:\Insight Data\QC-lot/level already exists. Do you want to replace?” Click “**Yes**” to replace.
11. Repeat above steps to save level 2 and 3.
12. Minimize screen and click on ***Insight*** icon, or click on icon on the bottom bar of the desk top.
13. Enter user email address and password.
14. Select “**Submit QC Data**.”
    1. Select analyzer as “**XS**” from drop down box.
    2. Click on **[Browse]** button.
    3. Highlight correct lot/level of current QC.
    4. Select “**Open**”.
    5. Click blue “**Submit Data File**” button.
    6. A message will appear highlighted in green that QC data file has been uploaded successfully, or highlighted in red if there is a problem that needs to be investigated
    7. Repeat above steps to upload levels 2 and 3.
15. Reviewing ***Insight*** report
16. After all three data files are uploaded, view report.
    * 1. Click on “**View QC Data Report**.”
      2. Check to ensure no data points are missed and that QC values are within SDI range.
17. Print report - Approximately 1 week after the closing date for QC submission, the QC report will be ready to print. The report will have a peer group analysis.
    1. Print a cumulative customer report from the Sysmex/*Insight* homepage. Select “**Customer QC Reports”** then “**View Reports**.”
    2. Select the appropriate analyzer, lot number, mode and type of report to be printed. Select “**Full Report with Raw Data**.” This report will show each run of QC for the analyzer.
    3. Select “**Cumulative P1 & P2**” for the final report. Give the final report to the lead tech to be reviewed and signed. The report is also to be reviewed and signed by the medical director.
    4. File the signed copy of the QC final report in the Sysmex QC binder.
18. A dialog box displays when analysis is complete.

**REFERENCES**

Sysmex XT-2000i/XT-1800i CLSI Procedure, January 2014.

Sysmex XT-4000i CLSI Procedure, January 2014.

Sysmex XE-5000 CLSI Procedure, January 2014.

Sysmex XS-1000i CLSI Procedure, January 2014.

Sysmex XE-2100 CLSI Procedure, January 2014.