Document Title: Quality Control Management for Sysmex XN-9000

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REVISION HISTORY

Procedure #	Revision Date	Reason for Revision
SH.CP.AU.hem.0129.0001		New
SH.CP.AU.hem.0129.0002	2/2/2018	Add XbarM management to address onsite CAP inspection deficiency – official documentation performed post inspection

Title: Quality Control Management for Sysmex XN 9000 Analyzer

I. PURPOSE

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

II. SCOPE

To be used by laboratory personnel at UR Medicine Labs at Strong Memorial Hospital, Hematology-Chemistry Lab.

III. RESPONSIBILITIES

Department and functional responsibilities are defined in the table below:

Group/Person	Responsibility
Quality Assurance	• Supports the development of this document.
Medical Director	• Ensures that the procedure is followed. • Review and approval of this document.
Supervisor	• Ensures that the procedure is followed. • Review and approval of this document.
End User	• Follows the procedure.

IV. SPECIMENS

Every two months a new lot of quality control material arrives at the lab. Each new lot must have target values determined for each level and each analyzer. The quality control material was originally human blood, but has been augmented to enhance longevity of the material.

V. QUALITY CONTROL

NOTE: XN CHECK® manufactured by Sysmex is a tri-level whole blood commercial control for use with the Sysmex XN hematology analyzer.

A. There are three levels of XN CHECK quality control material, low, normal and high, packaged in barcoded 4.5 ml vials.

B. Quality control is performed in order to monitor an analyzer's performance over time. XN CHECK and XN CHECK BF is the material used to monitor the performance of the XN analyzer. Quality control should be run in accordance to licensing agency regulations. 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 (see SH.CP.AU.hem.0127). Document results on appropriate log.

C. Quality Control Testing

1. Run controls according to local regulations or at least once each day that testing is to be performed. All QC levels will be run each shift the instrument(s) is operational.
2. Controls must be run after a calibration has been performed.
3. Controls must be run after specified service procedures are performed.
4. Controls must be run when new lots of Quality Control are received; a statistical workup is required, prior to its official use in the laboratory.
5. Each Shift is responsible for ensuring that all QC levels have been run and the instrument is operational prior to reporting patient results

VI. SPECIAL SAFETY PRECAUTIONS

A. All human source materials should be considered potentially infectious and must be handled with precautions used for human blood, as described in the CDC (Center for Disease Control) recommendations and in compliance with the Federal OSHA (Occupational Safety and Health Administration) Blood-borne Pathogen Standard, 29 CFR (Code of Federal Regulations) part 1910.1030. Follow specimen handling as outlined by Laboratory Safety Policy, SH.CP.AU.gen.0005.

VII. STORAGE AND STABILITY

A. *Sysmex* quality control material, *XN check*, is shipped every 56 days, with an 84 day closed vial product life.

B. Store XN check vials at 2-8 °C. Storage outside this temperature range risks damage. Open vial stability is 7 days. Per manufacturer do not add residual QC material to a new vial.

VIII. MATERIALS/REAGENTS FOR RUNNING COMMERCIAL CONTROLS

A. Sysmex XN-10 and IPU
B. Sample racks
C. Sysmex XN-10 reagents
D. Sysmex XN-Check control material – Levels 1, 2 & 3
E. Storage refrigerator at a temperature between 2-8 degrees C.

IX. PROCEDURE

NOTE: For details on how to run XN CHECK quality control material, refer to SH.CP.AU.hem.0127, Operation of the Sysmex XN9000

A. New lot registration:
1. Log into the IPU as admin. Login=admin, password=admin
2. From the Menu screen on the IPU, click the [QC File] button.
3. Use the tabs near the bottom of the screen to select an analyzer (Anakin, Obi-wan, Luke).
4. Select an available QC file number from the list.
5. On the tool bar, click [Regist.]
6. Enter the appropriate lot information:
   a. Material
   b. Lot Number
   c. Expiration Date
7. Click [Restore]
   a. Browse XN QC Limits folder on XN-IPU Desktop
   b. Select file for QC to be registered
   c. Select Open.
   d. Click and drag on the list of parameters to select all
   e. Click [Variable Target]
   f. Click [OK]
   g. Sysmex Range Limit %'s will automatically upload to the file
8. Repeat steps 2-7 for remaining levels on all analyzers.

B. New lot work up:

1. Data collection

   a. Parallel test new controls by analyzing the chosen levels of control, selected per lab policy QC protocol, a minimum of twice a day for 5 days prior to expiration of current lot.
   b. A minimum of 10 data points is required for work up to establish target range.
   c. Remove QC material from refrigerator and allow to come to room temperature.
   d. Mix 15 to 20 times by inversion
   e. Place the vials in the Red QC rack
   f. Place the rack on the feeder, the rack will be sent to each analyzer.
   g. Results will be plotted in the L-J chart as well as Radar for review.
   NOTE: *When a lot is in the work up phase, follow up for failed QC is not required*
   h. After a minimum of 10 data points are accumulated, auto set the targets.

2. Data review

   a. On the XN IPU
      1) From the Menu screen, click the QC File button

2) Select one the new lot QC level files
3) Click QC Chart
4) Select [Ref] from the toolbar and click Compare Analyzers
5) In the pop up box that appears be sure both analyzers are checked and click OK
6) Select [Range] from the toolbar and press and hold CRTL+A on the keyboard to select all the data points from the work up
7) Select [Output] and click Report GP

b. From the Sysmex Insight page
1) Log into to Sysmex and go to the Insight page
2) Click on [Customer QC reports] on the left side of the page
3) Use the Lot dropdown menu to select your new lot. When the screen refreshes only that lot for each analyzer will be listed.
4) Click [View Report w/Raw Data]
5) Print data
6) Review Insight report and XN QC reports to verify that targets are within manufacturer's ranges. The kit insert for that control lot can also be used.
NOTE: *If targets are not within manufacturer's range, consult with supervisor and Sysmex TAC before converting to the new lot.*
7) Compile all reports for all QC levels on all analyzers and Sysmex QC assay sheet to be signed off by supervisors.

C. Lot conversion: Autosetting target means (after a minimum of 10 data points are accumulated):
1. Log into the IPU as admin
2. From the Menu screen, click the [QC file] button
3. Use the tabs at the bottom of the screen to select an analyzer
4. Select a QC file of the new lot
5. Click [QC Chart]
6. Click [Range], press and hold CTRL+A on the keyboard to select all the data points for the work up
7. On the toolbar click [Modify]
8. Click and drag to select all parameters
9. Click [Auto Settings] button, only [Target] should be checked. De-select [Limit] if required.
10. Click [OK]. The target for each parameter will be calculated and set for the QC lot.
11. Click Close
12. Repeat steps 2 through 10 for remaining levels and analyzers

D. XbarM – Moving Patient averages

1. Establishing X-barM Limit%

a. During implementation of the XN9000 system, a minimum of 200 data points representing 4000 samples in 20 patient size batches was collected. Data was collected over multiple reagent lots and over a three

month period to include all types of patient samples normally encountered.

2. Batch size and review frequency

   a. X-barM can be monitored in lieu of a retained patient sample for a longitudinal control if 100 or more patients are run each day. Common batch size is 20; however, the Sysmex data center suggests using a larger batch size to allow about six points to be plotted per 24 hour period.

   b. Batch size for X-barM is defined below. Each point on the X-barM graph represents one batch:

CBC XbarM batch:	35
Diff XbarM batch:	35
Retic XbarM batch:	10
PLT-F XbarM batch:	10

3. Supervisor or designee will review X-barM charts daily.

X. LIMITATIONS: N/A

XI. CALCULATIONS: N/A

XII. INTERPRETATION: N/A

XIII. RESULT REPORTING

A. Insight data review:

Insight™ Quality Assurance Program (QAP) is a Sysmex web based peer data repository. Every QC data point is automatically transmitted to Sysmex Insight via SNCS. Each lot has two data submission dates, approximately every 30 days for the 84 day dated product. Period 1 and 2 start and end dates are on the QC assay sheet and QC lot calendar.

1. Log in at Sysmex.com
2. Click on Insight Login
3. Click on Customer QC reports
4. Use the Lot dropdown menu, select your lot. When the screen refreshes only that lot for each analyzer will be listed.
5. For each analyzer print out the desired data, period 1 or period 2, by clicking [View Report w/Raw Data]
6. File data in Sysmex QC wrap up binder by analyzer
7. Fill out the QC Review Documentation cover sheet, include Lot#, circle mid or end lot and include date range of data, Instrument type and serial number

8. Upon reviewing the Insight reports, add any comments under the appropriate analyzer column on the cover sheet. i.e., parameters with a negative or positive bias or running close to it.
9. Initial and date by your name on the cover sheet and pass along to supervisors.
10. Once all supervisors have reviewed signed and dated the QC review document hand the material over to QA/QC to be filed.

XIV. TRAINING

Personnel	Training Required
Management	Read
Technical Staff	Read Perform Knowledge Check and Skills Assessment upon initial training. Review and perform Knowledge check for significant changes

XV. REFERENCES

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

B. Sysmex America Inc., Lincolnshire, IL. Sysmex Insight Participant Overview Guide.

C. Sysmex XN-9000 CLSI Procedure, Document Number 1010-LSS, Rev. 1, March 2013.