EVALUATING NEW LOT NUMBERS OF CONTROLS

Policy

Most commercial controls have expected recovery ranges for each parameter, provided by the manufacturer. The mean of such ranges may not be the exact target value in a given laboratory. Each laboratory must assign its own initial target value, based on initial analysis of the material; this target value should fall within the recovery range supplied by the manufacturer, but need not exactly match the package insert mean. The laboratory must establish specific recovery ranges that accommodate known changes in product attributes, assuming that calibration status has not changed.

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

Materials

XN CHECK/BF Control Material for XN analyzers
XN 9000

Procedure

At least a week prior to the expiration of the current lot number of assayed control cells, do the following:

Registering a New Lot or Modifying a QC file – lot information input

Step	Action
1	Select **[QC File]** Icon.
2	Select **TAB** for analyzer from bottom of QC File screen.
3	Select File number to be registered.
4	Select **[Register]** button on toolbar.
5	Enter lot information: • Material • Lot Number • Expiration Date
6	Select **[Restore]**. 1. Browse XN QC Limits folder on XN-IPU Desktop 2. Select file for QC to be registered 3. Select Open 4. Sysmex Range Limit %'s will automatically upload to the file
7	Repeat for each level of XN CHECK, XN CHECK BF to be registered and for each module in the XN configuration.

Note: To modify an existing QC File, select the QC File and **[Modify]** from the toolbar. Update the Lot No, Exp. Date as appropriate.

Procedure, continued

Run the NEW QC

Step	Action
1	Run the new lot on different shifts for at least 5 days prior to expiration or previous lot.
2	After a minimum of 10 data points are accumulated, calculate the mean by performing **AUTO SET TARGET** on the XN.

Note: Refer to Hematology Policy & Procedures, 02-001 XN QC Procedure for detailed instructions on performing QC.

Auto Set Target Values

Step	Action
1	Select QC Chart.
2	Select **[Range]** and drag the flag so that every data point is included.
3	Select **[Modify]**.
4	Highlight all parameters and select **[Auto Setting]**.
5	Confirm that the check box for **TARGET ONLY** is set. Do not select the check box for LIMIT.
6	Select **[OK]**; the target for each parameter will be calculated and set for the duration of the QC lot.
7	Repeat steps for each new lot of QC being moved into production.
8	Confirm the target set falls within the range of means provided on the XN Check assay sheet provided.

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

Attachment A. Sysmex Evidence-Based Control Limits

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			