

## 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** *Refer to the safety manual for general safety requirements.*

**Materials** Sysmex XN-L CHECK Controls  
 Sysmex XN 550 analyzer

**Procedure** New QC lot crossover or parallel studies

At least a week prior to the expiration of the current lot number of assayed control cells, the new lot is analyzed in conjunction with the current QC lot. The BeyondCare Quality Monitor program establishes the target and limit values for the new QC lot once it has accumulated 10 data points.

### Registering a New Lot of QC- Manual Mode

Step	Action
1	Ensure Analyzer is in Manual Mode
2	Touch the manual icon to program the manual icon
3	Use the barcode scanner to read the barcode on the QC vial. The lot number will be automatically registered in the next available QC file
4	Verify the QC registration in the QC File list
5	Follow analyzer procedure for processing the new lot of QC material.
7	Repeat for each level of XN CHECK to be registered

### Registering a New Lot of QC- Sampler Mode

Step	Action
1	Ensure Analyzer is in Sampler Mode
2	Place the well mixed-vials of QC in a sample rack and start processing on the analyzer

## EVALUATING NEW LOT NUMBERS OF CONTROLS, Continued

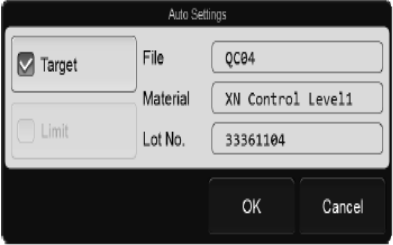
3	Upon reading the barcodes, the QC levels will automatically register in the next available QC files. Verify QC registration and results in the QC File list.
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Note: The analyzer must have an active SNCS connection.

### Run the NEW QC

Refer to *Hematology Policy & Procedures, 02-0010 XN 550 Quality Control Procedure* for detailed instructions on performing QC.

### Auto Set Target Values

Step	Action
1	Select QC Chart.
2	Select <b>[Range]</b> and drag the flag so that every data point is included.
3	Select <b>[Modify]</b> button on the toolbar; the <b>'Input Lot Information'</b> dialog box displays.
4	Select <b>[Target/Limit Settings]</b>
5	Select [Auto Settings]
6	<p>In the dialogue box that opens, check the box for target values to be automatically set, the touch <b>[ok]</b></p> <div style="display: flex; align-items: center;"> <div style="margin-right: 20px;"> <p>'Auto Settings' dialog box:</p>  </div> </div> <p>Note: This procedure only applies to laboratories who do NOT utilize the BeyondCare Quality Monitor for Hematology Application.</p>

## EVALUATING NEW LOT NUMBERS OF CONTROLS, Continued

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### Controlled Documents

The following controlled documents support this procedure.

Reference
Sysmex XN-550 <i>Instructions for Use</i> (North American Edition), Sysmex Corporation, Kobe, Japan.
Sysmex XN series <i>Administrator's Guide</i> (North American Edition), Sysmex Corporation, Kobe, Japan
Sysmex America Inc., Lincolnshire, IL. XN CHECK Hematology Control for Sysmex XN-Series Analyzers package insert

Related Documents
1. HEM 02-0010 XN Quality Control Procedure
2. Sysmex Evidence-Based Control Limits

**EVALUATING NEW LOT NUMBERS OF CONTROLS, Continued**

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Dir. Lab Ops reviewed/ date	Date change Implemented
New	New Procedure	Yvette Lingat 4/7/2020		Mary Lou Beaumont	4/28/2020