EVALUATE XBarM Quality Control

Introduction

The Sysmex XbarM quality control program collects batches of reliable (not necessarily normal) patient results and applies Dr. Brian Bull's formula to all the primary parameters as well as the sensitivity parameters. The algorithm produces a "weighted average" of patient data and is plotted in a QC chart. Standard statistical process control allows the stability of patient-based averages to be monitored and flagged. XbarM QC compliments the use of XN Check control material. Where control drift or matrix effect is an issue, XbarM may aid in determining if there are real quality issues by evaluating the effect on patient results.

Policy

XbarM is an internal quality control process used in conjunction with Sysmex XN Check QC to monitor the performance of the Sysmex XN Hematology Analyzers. Action is required when results fall outside the control limits.

Summary

The formula and calculations are incorporated into the computerized data analysis. This laboratory will establish XbarM (Xm) historical limit % using 200 data points, representing 4000 samples in 20 patient size batches. Historical Xm limits are collected over multiple reagent lots and at least one (1) month, including all types of patient samples normally encountered. Batch size for Xm will be 20 patient samples per batch. Each point on the Xm QC graph represents one batch. Each shift will review Xm charts when they run their daily QC. Manager will review Xm charts at least monthly.

Establishing the XBarM Control Program

Step	Action
1.	Click on the **[QC File]** icon in the Menu screen
2.	Click a tab and select an analyzer.
3.	Scroll to the bottom of the screen and select a **QC file [CBC, DIFF, RET, or PLT]**
4.	Click the **[Modify]** button on the toolbar.
5.	Target/Limits Settings • Highlight all the parameters listed in the "Target/Limit Settings" • Click on the **[Restore]** button which will open the "QC Limit%Rev03ver.19" window • Select the appropriate file (XBarM CBC Limits, XBarM DIFF Limits, XBarM PLT Limits, or XBarM RET Limits) **NOTE**: A pop-up window will appear if the incorrect file is chosen for the XBarM QC file being modified. • Click on the **[Open]** button, to close the window.
6.	Click **[OK]** button, to accept the changes.

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Set targets and limit values

Step	Action
1.	Click on the **[QC File]** icon in the Menu screen.
2.	Click a tab and select an analyzer.
3.	Scroll to the bottom of the screen and select a **QC file [CBC, DIFF, RET, or PLT]** and double click to open the QC Chart screen.
4.	Click on the **[Range]** icon in the toolbar and select n = 200 QC data points by dragging the range tool to the left.
5.	Click the **[Modify]** button on the toolbar.
6.	Highlight all the parameters listed in the "Target/Limit Settings."
7.	Click on the **[Auto Settings]** button.
8.	Place a **[√]** next to "Target" and "Limit."
9.	Click on the **[OK]** button to close the window.
10.	Click on the **[OK]** button to close "Input Lot Information."

New Reagent Lot Verification

Performance verification of new reagent lots and/or shipments may be accomplished by monitoring XbarM of reportable parameters.

Step	Action
1.	New lot of reagent installed on instrument.
2.	Review XbarM after the next two (2) batches of 20 samples. XbarM is the most sensitive method for detecting changes with a new lot of reagent.

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Trouble-Shooting results

Follow the steps below if the XbarM is out of limits.

Step	Action
1.	A red cross will flag on the XBarM chart.
2.	Check to make sure samples were run randomly and batches were not predominately Peds or Oncology patients. If samples were not a random population then document this in QC ACTION LOG.
3.	If XBarM continues to exceed limits with 2 or more red crosses, then check instrument calibration and precision by running one level (L1, L2 or L3) of XN Check QC.
4.	Visually inspect reagents to ensure they are installed correctly and to see if a new lot of reagent has recently been installed. Performance verification of new reagent lots and/or shipments may be accomplished by monitoring XBarM of reportable parameters.
5.	Investigate all unusual results. Resolve problems and document.
6.	Notify Hematology Manager, Sysmex Technical Assistance Hotline or Regional Laboratory Instrumentation if unable to correct problem.
7.	Document ALL troubleshooting performed in the QC ACTION LOG.

Reference

Sysmex, XN – Series Resource Manual
Document Number: 1002-LSS, Rev. 2 – February 2013
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