



STEM CELL LABORATORY (STCL)



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DOCUMENT TITLE:

Sysmex XN-450 QC Review Log - Weekly and Monthly

DOCUMENT NOTES:

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Control Information

Author: WATER002

Owner: WATER002

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SYSMEX XN-450 QC Review Log – WEEKLY / MONTHLY

Date	Problem Identified	Correction actions taken to resolve problem(s)	Tech Initials

Weekly Review: (Initials/Date) Wk1 _____ Wk2 _____ Wk3 _____ Wk4 _____ Wk5 _____
Monthly Review: (Initials/Date) _____

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Instructions for Sysmex XN-450QC Review – Weekly / Monthly

On the form record the lot # and implementation date of that lot #; if a second lot # is implemented during a month, enter the second lot # and implementation date in the fields provided.

When a QC parameter does not produce satisfactory results, corrective action /an investigation must be performed to determine whether there is an instrument malfunction, a problem with the QC material, or technical error. The investigation must be complete before reporting out any patient-related test results.

QC GUIDELINES:

- IF one level of QC for any parameter(s) is (are) outside the 2SD limit, QC should be reanalyzed.
 - IF repeat QC is **within 2SD range**, patient results can be reported.
 - If the repeat QC value(s) is **outside the 2SD range**, the LJC QC data must be reviewed for all three (3) levels of QC material.
 - If there are NO previous outliers and the last five (5) or more QC values are evenly distributed around the mean, repeat QC using a fresh vial.
 - If repeat fresh QC is within 2SD, patient results can be reported.
 - If repeat fresh QC is outside 2SD, do NOT report patient results and consult senior staff for troubleshooting options.
 - If there are previous outliers OR if previous QC values are falling on one side of mean, bring this to the attention of senior staff for troubleshooting options. Do NOT report patient results until QC values fall within the 2SD range.
- IF two or more levels of QC for any parameter are outside the 2SD limit, STOP patient analysis and troubleshoot. Patient results can NOT be reported until results are within the 2SD limit.
- When the last 5 or more QC values for any parameter are found to be plotting on the same side of the mean for two or more levels of QC material, inform the senior staff. If the parameters are plotting within the 2SD limit, patient results may be reported.

Record any /all correction action on the troubleshooting log.

Weekly and monthly reviews must be completed.

Signature Manifest**Document Number:** STCL-EQUIP-023 FRM3**Revision:** 01**Title:** Sysmex XN-450 QC Review Log - Weekly and Monthly**Effective Date:** 20 Mar 2025

All dates and times are in Eastern Time.

STCL-EQUIP-023 FRM3 Sysmex XN-450 QC Review Log - Weekly and Monthly**Author**

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Document Release

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Amy McKoy (ACM93)	Document Control Specialist	20 Mar 2025, 01:37:45 PM	Approved