



STEM CELL LABORATORY (STCL)



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DOCUMENT TITLE:

Sysmex XS QC Review Log - Weekly and Monthly FRM3

DOCUMENT NOTES:

Document Information

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Control Information

Author: WATE02

Owner: WATE02

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Equipment: Sysmex XS-1000i;
SN: 62814
Location: Cell Processing
Year: _____

STCL-EQUIP-002 FRM3 **SYSMEX XS-1000i QC Review Log – WEEKLY / MONTHLY**

Month: _____

Initial QC review as performed

Record problems and corrective action on reverse side

Lot # _____ Implementation Date: _____ Lot # _____ Implementation Date: _____

NP = NOT Performed N/A = NOT Applicable

	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
WEEKLY																															
Print Levy Jennings Charts for all three (3) levels of Quality Control inclusive of all data points to date (ie. Week 3 should include data points for weeks 1, 2, and 3).																															
Review each parameter on all three (3) levels of controls to ensure corrective action was taken for any OUTLIERS (See INSTRUCTIONS or SOP for details).																															
Review each parameter on all three (3) levels of controls to look for analytical imprecision (ie. bias). Record corrective action, if applicable, on troubleshooting log.																															
File printed weekly Levy Jennings Charts in designated location.																															
MONTHLY																															
Review printed Levy Jennings Charts from Weeks 1, 2, 3, and 4 to ensure that any/all corrective actions, if applicable, were taken and documented on the appropriate troubleshooting log.																															
Tech Initials																															

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

Monthly Review: (Initials/Date) _____

STCL-EQUIP-002 FRM3
SYSMEX XS-1000i QC Review Log – WEEKLY / MONTHLY
Troubleshooting Log

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) _____

Instructions for Sysmex XS-1000i QC Review – Weekly / Monthly FRM3

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. As long as 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-002 FRM3**Revision:** 02**Title:** Sysmex XS QC Review Log - Weekly and Monthly FRM3**STCL-EQUIP-002 FRM3 Sysmex XS QC Review Log - Weekly and Monthly FRM3****Author Approval**

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		04 Jan 2013, 03:53:20 PM	Approved

Manager Approval

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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
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QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		07 Jan 2013, 10:48:32 AM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Sharon Hartis (SH259)		07 Jan 2013, 10:48:33 AM	Email Sent
Linda Sledge (SLEDG006)		07 Jan 2013, 10:48:33 AM	Email Sent
Barbara Waters-Pick (WATE02)		07 Jan 2013, 10:48:33 AM	Email Sent
System Administrator (SYSADMIN)		07 Jan 2013, 10:48:33 AM	Email Sent