STEM CELL LABORATORY (STCL)

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DOCUMENT TITLE:

Sysmex XS-1000i QC Review Log

DOCUMENT NOTES:

Number changed to from STCL-EQUIP-006 to STCL-EQUIP-002 Form 1

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Control Information

Author: WATE02	**Owner:** WATE02
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Equipment: Sysmex XS-1000i
SN: 62814
Location: Cell Processing

SYSMEX XS-1000i QC Review Log - DAILY

Mark Y or N by each entry and Initial QC review as performed. **Month: _____** **Year: _____**

Record problems and corrective action on reverse side. **N/A = Not Applicable** **NIU = Instrument Not in Use**

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

Instructions for handling QC Material:

Remove Sysmex E-Check QC vials from refrigerator; allow the vials to come to room temperature for ~ 15 minutes. Mix the vials by gentle end-to-end inversion until the cell button in the bottom of each vial is completely suspended.

	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
DAILY																															
1st Shift																															
Level 1 QC, OK? Y or N (If N(o), complete QC trouble shooting log on reverse page with details)																															
Tech Initials																															
Level 2 QC, OK? Y or N (If N(o), complete QC trouble shooting log on reverse page with details)																															
Tech Initials																															
Level 3 QC, OK? Y or N (If N(o), complete QC trouble shooting log on reverse page with details)																															
Tech Initials																															
2nd Shift																															
Level 1 QC, OK? Y or N (If N(o), complete QC trouble shooting log on reverse page with details)																															
Tech Initials																															
Level 2 QC, OK? Y or N (If N(o), complete QC trouble shooting log on reverse page with details)																															
Tech Initials																															
Level 3 QC, OK? Y or N (If N(o), complete QC trouble shooting log on reverse page with details)																															
Tech Initials																															

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

Monthly Review: (Initials/Date) _____

*** QC is performed on 2nd shift only if analyzer is in use for more than 8 hours**

STCL-EQUIP-002 (FRM 1) Sysmex XS-1000i QC Review - DAILY Troubleshooting Log

Date	Outlier (including the Level of QC and the Parameter)	Result obtained	Lot # / Action Taken	Tech Initials

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

Monthly Reviews/Date and Initial: _____

Instructions for Sysmex XS-1000i QC Review – DAILY (FRM 1)

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

It is VERY important that the QC material be handled exactly according to the instructions. This will ensure that the samples have time to equilibrate to room temperature and are mixed adequately before they are tested. Handling the QC material consistently at all times will minimize the number of variables that need to be investigated if/when parameters are out of acceptable limits.

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.

The date the problem was encountered, the outlier (including the parameter and level of QC), the result of that parameter, the Lot #, action taken, and the initials of the tech identifying the problem must be documented.

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.

Signature Manifest

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Title: Sysmex XS-1000i QC Review Log

STCL-EQUIP-002 (FRM1) XS-1000i Rev

Author Approval

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