



STEM CELL LABORATORY (STCL)



DOCUMENT NUMBER: STCL-EQUIP-002 JA5

DOCUMENT TITLE:

Sysmex XS-1000i Hematology Analyzer Precision and Calibration Checks

DOCUMENT NOTES:

Document Information

Revision: 01

Vault: STCL-Equipment-rel

Status: Release

Document Type: Equipment

Date Information

Creation Date: 04 Mar 2015

Release Date: 08 Apr 2015

Effective Date: 08 Apr 2015

Expiration Date:

Control Information

Author: WATE02

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Previous Number: None

Change Number: STCL-CCR-279

STCL-EQUIP-002 JA5 SYSMEX XS-1000i HEMATOLOGY ANALYZER PRECISION AND CALIBRATION CHECKS

1. PRECISION CHECK

- 1.1. Perform routine daily and weekly maintenance on the instrument, and perform a background count to ensure counts are within acceptable limits.
- 1.2. Verify that there is sufficient volume of all reagents. Precision and Calibration procedures will be aborted if the Sysmex XS-1000i runs out of reagent.
- 1.3. Obtain a sample of fresh normal whole blood. Do not use commercial controls or calibrators for precision. The blood donor specimen should:
 - 1.3.1. Be free from medication, and interfering substances such as lipemia, icterus, platelet clumps, hemolysis, etc.
 - 1.3.2. Have morphologically and numerically normal CBC.
 - 1.3.3. Be drawn in EDTA anticoagulant tube using proper collection technique.
 - 1.3.4. Be a minimum of 2 mL of sample.
- 1.4. On the IPU, click [Menu] or press [F4].
- 1.5. Click on the "Controller" icon in the Menu window.
- 1.6. Double click on the "Precision Check" icon on the Controller menu.
- 1.7. Attach appropriate tube adapter to the sample position.
- 1.8. Place the well-mixed sample tube in the tube position.
- 1.9. Analyze the sample 11 times in the Manual Mode, mixing gently before each analysis. After each analysis, the results display on the IPU screen, and the cursor moves to the next line.
- 1.10. The mean, SD, and CV% are calculated on the last 10 analyses. The CV% values are displayed in red if they exceed the Precision Limit %. If the CV% exceeds the precision Limits, click [CANCEL].
- 1.11. If all results are within Precision Limits, click [OK] on the Precision Check screen to save the data and close the Precision Check window.
- 1.12. To print a hard copy of the Precision results, click on "Precision Check List" on the "Controller" screen, then click [File] on the Menu Bar and click [Print].

2. CALIBRATION CHECK

- 2.1. Prepare the Sysmex SCS-1000 calibrator according to the product insert.
- 2.2. SCS-1000 Calibrator is a secondary whole blood calibrator for use with the XS-1000i hematology analyzer. Assay values for primary parameters are traceable to reference methods.
- 2.3. SCS-1000 consists of human red and white blood cells with a platelet component suspended in fluid medium. Each vial contains 2.0 mL of calibrator material.

- 2.4. Store vials in the upright position, at 2-8° C. Do not freeze or expose to excessive heat. Unopened and properly stored, SCS-1000 is stable until the expiration date stated on the vial. Open vial stability is 4 hours.
- 2.5. Storage outside of 2-8° C can damage Sysmex SCS-1000 causing deterioration that risks inaccurate calibration. If deterioration is suspected, call the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX).
- 2.6. Use of the product at environmental temperatures that exceed 86° F (30° C) can reduce calibration accuracy.
- 2.7. Click [Menu] or press [F4].
- 2.8. Click the “Controller” icon on the Main menu window.
- 2.9. Double-click the “Calibrator Calibration” icon on the Controller menu.
- 2.10. Click [ASSAY TARGET], then click in the parameter fields and use the numeric keys to enter the target values for each parameter from the Sysmex SCS-1000 assay sheet. Click in the next field after each entry. Click [OK] when all values have been entered.
- 2.11. Attach the appropriate sample tube adapter.
- 2.12. Remove the cap from the calibrator vial and perform 6 consecutive analyses in the sampling mode. Do not mix in between 6 analyses. Wait until the 6th analysis is complete, and then review results.
- 2.13. After 6 analyses, the last 5 analyses are used to calculate the Range Values and Delta percents. The parameter values are highlighted in red if they are out of range.
- 2.14. Calibration cannot be performed if the Range Value exceeds the Max Range Value, or if the Delta % exceeds the Service limit. Take corrective action. See Troubleshooting section, in the Sysmex XS-Series Instructions for Use manual.
- 2.15. If the Range Values and Delta Percents are within acceptable limits and require calibration, click [ACCEPT]. The parameters are displayed with a check in the check box beside the new Compensation Rates. Parameters that are not within acceptable limits cannot be selected for calibration.
- 2.16. Click [OK] to execute the calibration or [Cancel] if calibration is not desired or necessary. The display returns to the Controller menu.
- 2.17. Using another fresh vial of the calibrator, verify the calibration by repeating the Calibration Check procedure. The analyzed values should all be within acceptable limits. Do not execute calibration; exit the Calibration function.
- 2.18. Print the Calibration History.
- 2.19. Click [Menu] or press [F4].
- 2.20. Click the “Controller” icon.
- 2.21. Click the “Calibration History” icon.
- 2.22. Click on the calibration date in the Calibration History list.

- 2.23. To print a hard copy of the Calibration results, click on Calibration Check List on the “Controller” screen, then click [File] on the Menu Bar and click [Print].
- 2.24. Following calibration, analyze commercial controls. Adjust target values if necessary.

Signature Manifest**Document Number:** STCL-EQUIP-002 JA5**Revision:** 01**Title:** Sysmex XS-1000i Hematology Analyzer Precision and Calibration Checks

All dates and times are in Eastern Time.

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Document Release

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