STEM CELL LABORATORY (STCL)

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Sysmex XS-1000i Hematology Analyzer for the Stem Cell Laboratory

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STCL-EQUIP-002
SYSMEX XS-1000*i* HEMATOLOGY ANALYZER AUTOMATED BLOOD COUNT PROCEDURE FOR THE STCL

1 PURPOSE

1.1 The purpose of this procedure is to provide users with basic instructions regarding the proper use and operation of the Sysmex XS-1000i Automated Hematology Analyzer.

1.2 Users should consult the *Sysmex XS-1000i Instructions for Use Manual,* as needed, for additional information.

2 INTRODUCTION

2.1 The Sysmex XS-1000i ™ is a quantitative automated hematology analyzer for in-vitro diagnostic use for determining 21 hematological parameters. The analyzer directly measures the WBC, RBC, HGB, HCT, PLT, NEUT#, LYMPH#, MONO#, EO#, and BASO #. The remaining parameters are calculated or derived: MCV, MCH, MCHC, RDW-CV, RDW-SD, MPV and differential percentages.

2.2 The Sysmex XS-1000i counts and sizes red blood cells (RBC) and platelets using electronic resistance detection enhanced by hydrodynamic focusing. Hematocrit is measured as the ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin is converted to SLS-hemoglobin and is read photometrically.

2.3 White Blood Cell (WBC) count and differential are evaluated using flow cytometry with a semiconductor laser utilizing scattered light and fluorescence to determine the differences in cell size, complexity and RNA/DNA content. The WBC differential channel classifies neutrophils, lymphocytes, monocytes, eosinophils, and basophils by cellular complexity and nucleic acid content. The differential cell placement is then enhanced utilizing Adaptive Cluster Analysis.

2.4 The Sysmex XS-1000i performs all aspirations using a single aspirator.

3 SCOPE AND RESPONSIBILITIES

3.1 The Stem Cell Laboratory medical directors, Stem Cell Laboratory manager, and employees of the Stem Cell Laboratory who use this equipment are responsible for ensuring the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

4.1	WBC	White Blood Cell
4.2	RBC	Red Blood Cell
4.3	HGB	Hemoglobin
4.4	HCT	Hematocrit
4.5	PLT	Platelet

4.6	NEUT	Neutrophil
4.7	LYMPH	Lymphocyte
4.8	MONO	Monocyte
4.9	EOS	Eosinophil
4.10	BASO	Basophil
4.11	MCV	Mean Corpuscular Volume
4.12	MCH	Mean Corpuscular Hemoglobin
4.13	MCHC	Mean Corpuscular Hemoglobin Concentration
4.14	RDW-SD	Red Cell Distribution Width-Standard Deviation
4.15	RDW-CV	Red Cell Distribution Width – Coefficient of Variation
4.16	MPV	Mean Platelet Volume
4.17	RNA/DNA	Ribonucleic Acid / Deoxyribonucleic Acid
4.18	EDTA	Ethylenediaminetetraacetic Acid
4.19	CPD	Citrate Phosphate Dextrose
4.20	ACD-A	Anticoagulant Citrate Dextrose Solution A
4.21	STCL	Stem Cell Laboratory
4.22	°C	Degrees Celsius

5 MATERIALS

5.1 Supplies

5.1.1 Test tubes

5.1.2 Deionized water

5.1.3 Clorox™ bleach, diluted to 5% concentration (use when CELLCLEAN is indicated)

5.1.4 e-CHECK™ commercial controls, 3 levels (Low, Normal, and High)

5.1.5 e-CHECK consists of human red and white blood cells with a platelet component suspended in fluid medium.

5.1.5.1 Store vials at 2-8° C. Do not freeze or expose to excessive heat. Unopened and properly stored e-CHECK is stable until the expiration date stated on the vial.

5.1.5.2 Open vial stability is 7 days when promptly refrigerated after each use. Record the open date, open expiration date and technologist's initials upon vial opening.

5.1.5.3 Heat or freezing can damage e-CHECK without gross visible changes. Moderate hemolysis can be normal. Deterioration is suspected when the mean of the control results is not within the assay expected ranges after appropriate troubleshooting. If

deterioration is suspected, call the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX).

5.2 Reagents

5.2.1 Four Sysmex reagents are used on the Sysmex XS-1000i.

5.2.2 All reagents are used at room temperature and are to be used (unopened) within the manufacturer's expiration date on each container.

5.2.3 When container is placed on the instrument, record the date the reagent was placed into use, the open expiration date and the performing technologist's initials on the container.

5.2.4 All reagents are azide free and they are intended for in vitro diagnostic use only.

5.2.5 Refer to STCL-EQUIP-002 JA2 Sysmex XS-1000i Hematology Analyzer Reagent Replacement for instructions for replacing reagents on the analyzer.

5.2.6 Reagent Verification is not a stand-alone documented process. Several systems are used together to verify reagent consistency from cube to cube and from lot to lot. The following programs validate the reagent/instrument system: 1) daily background checks, 2) the IPU reagent log, 3) the moving average QC file (selected parameters used primarily by the service representative), 4) the commercial control files which are compared across peer groups using ILQC and Insight programs, 5) the XS-1000i problem log.

NOTE: Do not ingest. Avoid skin and eye contact. In case of skin contact, wash immediately with plenty of soap and water. In case of contact with eyes, flush with plenty of water immediately. Consult with a physician in case of ingestion and/or eyes contact.

Reagent	Abbreviation	Storage Temperature	Open Expiration
CELLPACK	EPK	5 - 30° C	60 days
STROMATOLYSER-4DL	FFD	2 – 35° C	60 days
STROMATOLYSER-4DS	FFS	2 - 35° C	60 days
SULFOLYSER	SLS	2 - 30° C	60 days

5.2.7 CELLPACK is a clear and colorless whole blood diluent for use in the determination of hemoglobin and impedance counting and sizing of blood cells. It also forms a laminar sheath flow around the diluted sample for hydrodynamic focusing of the RBC and PLT. Do not use if there are signs of reagent contamination or color change. If reagent is frozen, thaw, mix thoroughly and allow bubbles to disperse before use.

5.2.8 STOMATOLYSER-4DL is a clear and odorless lysing reagent and diluent for the enumeration of NEUT, LYMPH, MONO, EO and BASO after eliminating RBC stroma. Do not use reagent if frozen or there are signs of contamination or color change.

5.2.9 STOMATOLYSER-4DS is a blue viscous staining reagent with a faint odor used to stain leukocytes in diluted, lysed blood for the determination of the 5-part differential including NEUT, LYMPH, MONO, EO and BASO. Do not use if frozen or there are signs of contamination or color change.

5.2.10 SULFOLYSER is a clear, odorless RBC lysing reagent that releases the hemoglobin to be measured by SLS hemoglobin method. Do not use if there are signs of reagent contamination or color change. If reagent is frozen, thaw and warm reagent in a 30° C water bath to dissolve ingredients completely and mix thoroughly before use.

5.3 Specimen

5.3.1 Samples may be comprised of peripheral whole blood, umbilical cord blood, granulocytes, bone marrow or peripheral blood progenitor cells collected in EDTA, Heparin, CPD, Sodium Heparin or ACD-A anticoagulants.

5.3.2 Allow refrigerated samples to come to room temperature and mix well before analysis.

5.3.3 The white counts from these samples are verified by comparison with the flow cytometer count.

5.3.4 Alert values and general hematology corrective action and follow up procedures are not applicable in the STCL given the nature of the cellular products being tested.

6 EQUIPMENT

6.1 Sysmex XS-1000i Hematology Analyzer

7 SAFETY

7.1 Wear all applicable personal protective equipment when handling potentially infectious blood and body fluids to include, but not limited to, gloves, lab coat, etc.

8 PROCEDURE

8.1 Calibration

8.1.1 Initial calibration is performed during installation and verified biannually during preventive maintenance by the Sysmex Field Service Representative. Calibration compensates for any bias inherent to the pneumatic, hydraulic and electrical system that may affect the accuracy of results. Calibrators traceable to reference methods are used in the calibration of the instrument. WBC differential parameters are calibrated in the factory prior to shipment and verified by the field representative upon installation.

8.1.2 The field service representative verifies calibration every six months or on an "as needed" basis to ensure accuracy of system.

8.1.3 Calibration is also required if one or more of the following occur:

8.1.3.1 Critical parts are replaced such as manometers, apertures or detector circuit boards.

8.1.3.2 Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.

8.1.3.3 When advised by field service representative.

8.1.4 Calibration verification may include review and documentation of acceptable performance on all three levels of commercial control and Xm QC data, proficiency testing results, inter-laboratory patient control testing and periodic exchange of donor bloods.

8.2 Start Up

8.2.1 Check pneumatic trap for fluid and drain if necessary.

8.2.2 Check reagent boxes for sufficient run volume.

8.2.3 Check printer paper supply.

8.2.4 Power Up Sequence

8.2.4.1 Press power switch on Information Processing Unit (IPU). IPU log on must be done before powering up the Main Unit.

8.2.4.2 Sysmex XS-1000i program log-on box displays. Log on the IPU with your User Name (STCL, our Lab pneumonic) and press [ENTER]. No password is required.

8.2.5 Press the power switch on right side of the Main Unit.

8.2.6 The instrument automatically performs self-check on the microprocessor, mechanical parts, temperatures and background counts.

Sysmex XS-1000*i* Acceptable Background Counts	
Parameters	**Acceptable Limit**
RBC	0.02×10^{12}/ L
HGB	0.1 g/dL
PLT	10×10^{9}/ L
WBC – C	0.1×10^{9}/ L
WBC – D	0.1×10^{9}/ L

8.2.7 Press the power switch on the printer, if necessary.

8.3 Analyze Commercial Quality Control Materials

8.3.1 All three levels of e-CHECK (L, N, and H) are tested in the closed mode at the beginning of each shift or are run once each eight hours of analyzer use.

8.3.1.1 Remove vials from refrigerator and allow them to come to room temperature for approximately 15 minutes.

8.3.1.2 Mix vials by gentle end to end inversion until the cell button in the bottom of the vial is completely suspended.

8.3.1.3 Place a Sysmex rack in the rack position of the Sampler with the notch on the rack to the right.

8.3.1.4 Place the well-mixed control vials in positions 8, 9, 10 of the Sysmex rack.

8.3.1.5 Attach the appropriate sample tube adapter, if necessary.

8.3.1.6 Close the Sampler cover.

8.3.1.7 Click **[Sampler]** or press **[F3]**.

8.3.1.8 The Sampler Sample No. dialog box displays. Click on the starting position for the rack and tube position in which the vials have been placed.

8.3.1.9 Press the sampler **Start** switch on the left side of the Main Unit.

8.3.1.10 A dialog box displays when analysis is complete.

8.3.1.11 Complete form STCL-EQUIP-002 FRM2 Sysmex XS-1000i Maintenance Log.

8.4 Review QC L-J Charts

8.4.1 On the IPU, click [QC Files] or press [F5].

8.4.2 Double click on the file to be reviewed. The Levy-Jennings chart will be displayed.

8.4.3 Results outside of acceptable limits are displayed with a red "X" on the L-J chart. The parameter name and the result value will be displayed with a red background.

8.4.4 Scroll through the screens to view all parameters by using the scroll bar on the right of the screen or press the down arrow.

8.4.5 Verify that all parameters fall within established limits. If a parameter falls outside the established limits, do not test or report patient results. For troubleshooting refer to and complete STCL-EQUIP-002 FRM1 Sysmex XS-1000i QC Review Log - DAILY.

8.5 Weekly/Monthly Review of QC

8.5.1 Print L-J graphs for each control level weekly. Date range should be set from date of QC implementation to the current date.

8.5.2 Graphs will be analyzed and any significant findings documented for each control level directly on the printout.

8.5.3 A significant finding would include the following:

8.5.3.1 Three consecutive days outside of +2 SD for a particular analyte or assay.

8.5.3.2 Trends identified where a particular control runs along the upper or lower limits instead of the mean.

8.5.3.3 Multiple assays reported outside of + 2SD in the same control level repeated over two consecutive days.

8.5.3.4 Significant findings will be reported to the laboratory supervisor and/or manufacturer technical support as needed.

8.5.3.5 Complete STCL-EQUIP-002 FRM3 Sysmex XS-1000i QC Review Log – Weekly/Monthly.

8.6 Patient Sample Processing

8.6.1 **MANUAL MODE** – (20 µL aspirated sample volume) minimum of 200 µL in tube or 90 µL in a micro-sample container. **NOTE**: STCL samples typically contain ~200 µL.

8.6.1.1 On the IPU, click **[Manual]** or press **[F2]**.

8.6.1.2 Enter the specimen number (alpha or numeric characters) using the keyboard or using the handheld bar code reader.

8.6.1.3 Click CBC+Diff.

8.6.1.4 Click **[OK]**.

8.6.1.4.1 Attach appropriate sample tube adapter, if necessary.

8.6.1.4.2 Mix the sample appropriately.

8.6.1.4.3 Place the sample in the sample tube adapter. If the sample has a cap, it is not necessary to remove it unless it is non-pierceable.

8.6.1.4.4 Press **Start** switch. (Inside the sampler cover on the XS-1000i with Sampler.)

8.6.1.4.5 When Ready the LED is lit green, repeat steps 8.4.1.1 - 8.4.1.9 for each additional sample.

8.6.2 **SAMPLER MODE** with Bar Codes – XS-1000i with Sampler (20 µL aspirated sample volume). A minimum of 1.0 mL of blood is required in the tube for the sampler mode.

8.6.2.1 Place a Sysmex rack in a rack position of the Sampler with the notch on the rack to the right.

8.6.2.2 Place up to 2 racks at one time (only if > 10 samples).

8.6.2.3 Place bar coded specimens in the rack. Ensure that labels are smooth with no loose edges.

8.6.2.4 Attach the appropriate sample tube adapter, if necessary.

8.6.2.5 Close the Sampler cover.

8.6.2.6 On the IPU, click **[Sampler]** or press **[F3]**. The Sample number dialog box displays.

8.6.2.6.1 Click on the starting position for the rack and tube position in which the tubes have been placed. Press **[OK]**.

8.6.2.6.2 Press sampler **Start** switch on the left side of the Main Unit.

8.6.2.6.3 The Sysmex XS-1000i automatically mixes the sample 10 times, aspirates, and analyzes the sample. Results print as they are completed if auto-output is selected.

8.6.2.6.4 A dialog box displays when analysis is complete.

8.7 Calculations

8.7.1 If making a dilution of the patient specimen and NOT running in the capillary mode, multiply measured parameters by the dilution factor and recalculate indices.

8.7.2 Limitations of Procedure

8.7.2.1 Sysmex XS-1000i Linearity

Parameter	Range	Units
WBC	0.3 - 400	$x10^9$/L or $x10^6$/mL
RBC	0.0 - 8.0	$x10^9$/L
HGB	0.0 - 25.0	g/dL
HCT	0.0 - 60.0	%
PLT	0.0 - 2000	$x10^9$/L

8.7.2.2 Values > upper limit:

8.7.2.2.1 Parameters that exceed these limits are flagged with @ beside the result. The sample must be diluted, rerun and multiplied by the dilution factor. Dilutions may be run immediately following preparation but within 30 minutes of dilution.

8.7.2.2.2 Note the use of dilution for linearity.

NOTE: WBC counts above 100 $x10^9$/L may falsely elevate the hemoglobin measurement. They may also falsely increase the RBC count, MCV and Hct.

8.7.2.3 Values < lower limit:

8.7.2.3.1 Check sample for clots or fibrin. (Request recollect if applicable.)

8.7.2.3.2 Perform background check to ensure that background is at a minimum.

8.7.2.3.3 Check previous results when available.

8.7.2.3.4 Perform film review and count estimates if low count is PLT and is less the 100 x 109/L.

8.7.2.4 Clotted Samples or Sample with Fibrin Strands

8.7.2.4.1 Samples with clots or fibrin are unacceptable. Some counts or all counts may be affected by the clotting process.

8.7.2.4.2 Call the appropriate collection site and request that the sample be recollected if applicable. If sample is unable to be recollected, consult with STCL Medical Director for further instruction.

8.7.3 Acceptable Reporting Format

8.7.3.1 Reporting Abnormal Results to Physicians

8.7.3.1.1 Abnormal/unexpected results are reported to Medical Director and/or attending physician as appropriate. Results may require follow-up action, based upon Medical Director or designee instruction, prior to release of product.

8.7.3.2 Alert Values/Corrective Actions:

8.7.3.2.1 Alert values and general hematology corrective action and follow up procedures are not applicable in the STCL given the nature of the cellular products being tested. If the STCL instrument is being used as a backup by another laboratory, they should refer to their own procedures regarding value reporting.

8.7.3.3 Instrument Flags:

8.7.3.3.1 When histogram and/or instrument flags are obtained, appropriate follow-up action to confirm results is required before reporting patient's results. **NOTE**: Every instrument ERROR Message requires follow up action. See instrument manual troubleshooting section.

8.7.3.4 Unusual results found on blood film examination may require review by the STCL medical director or patient attending physician.

8.8 Shut Down - Performed Daily (to clean the detector and dilution lines)

8.8.1 Click **[Menu]** or press **[F4]**.

8.8.2 Double click on the "Shutdown" icon.

8.8.3 After 2 minutes, a dialog box on the IPU displays "Please power off the analyzer".

NOTE: To continue analysis, click **[RESTART]** from XS-1000*i* Shutdown screen. After auto-rinse and background check is completed, XS-*1000i* is "Ready".

8.8.4 Power OFF the Sysmex XS Main Unit.

8.9 Power off the IPU – Performed Weekly

8.9.1 Click **[File]** from the menu bar, then click **[Exit]**.

8.9.2 Dialog box displays "Do you really want to Log off?" Click **[OK].**

8.9.3 Click on **Start** button at the bottom of Windows desktop.

8.9.4 Click [Shut Down].

NOTE: The Restart key displays on this dialog box. If desired, click **[RESTART]** to begin IPU start up process.

8.9.5 The system displays: "Please wait while the system writes unsaved data to the disk".

8.9.6 Record "shut down" on Maintenance Log.

8.10 Monthly Maintenance

8.10.1 Refer to Sysmex XS-Series Instructions for Use manual, Chapter 9 for detailed, illustrated procedures.

8.10.2 Important Note for ALL Maintenance

NOTE: CLOROX ULTRA is a 6% (by volume) Sodium Hypochlorite solution. The Sysmex *XS-Series Instructions for Use* manual recommends using a 5% Sodium Hypochlorite solution as a stock solution for maintenance procedures. To make 50 mL of 5% stock solution from CLOROX ULTRA, use the formula below:

To make 50 mL of 5% from 6% Sodium Hypochlorite:

(Conc. 1) x (Vol. 1) = (Conc. 2) x (Vol. 2)

Example: (6%) x (Vol 1) = (5.00%) x (50 mL)

V1 = 250/6

V1 = 42 mL bleach

Thus 42 mL of bleach and 8 mL of deionized water will make 50 mL of 5% Sodium Hypochlorite solution. Store stock 5% bleach in a dark place to prevent solution degradation from exposure to light.

8.10.3 Perform the rinse sequence monthly or every 1200 cycles to clean the optical detector block.

8.10.3.1 Click **[Menu]** or press **[F4].**

8.10.3.2 Click "Controller" icon on the menu screen.

8.10.3.3 Click "Maintenance" icon. The maintenance screen displays.

8.10.3.4 Click on "Monthly Rinse". The Monthly Rinse dialog box displays.

8.10.3.5 Attach the appropriate sample tube adapter.

8.10.3.6 Place a tube of 5% Sodium hypochlorite solution (CELLCLEAN) in the tube adapter.

8.10.3.6.1 Press the **Start** switch (located inside the sampler cover on the XS-1000i with Sampler) to initiate the cleaning.

8.10.3.6.2 Record on STCL-EQUIP-002 FRM2 Sysmex XS-1000i Maintenance Log.

8.10.3.6.3 The Power Off dialog box displays when the process is complete.

8.10.3.6.4 Press [Restart] to resume operation or power off the instrument.

8.11 Procedure Notes

8.11.1 Analysis of the specimen on the Sysmex XS-1000i is recommended before removing the cap to make a smear.

8.11.2 DO NOT PLACE samples on a mechanical rocker. Excessive mixing may induce platelet clumping and alter white cell membranes resulting in false interpretive messages.

8.11.3 For troubleshooting specifics refer to the Sysmex XS-Series Instructions for Use manual.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-EQUIP-002 FRM1 Sysmex XS-1000i QC Review Log - DAILY

9.2 STCL-EQUIP-002 FRM2 Sysmex XS-1000i Maintenance Log

9.3 STCL-EQUIP-002 FRM3 Sysmex XS-1000i QC Review Log – Weekly / Monthly

9.4 STCL-EQUIP-002 JA1 Sysmex XS-1000i Automated Hematology Analyzer Quality Control Management

9.5 STCL-EQUIP-002 JA2 Sysmex XS-1000i Hematology Analyzer Reagent Replacement

9.6 STCL-EQUIP-002 JA3 Sysmex XS-1000i Hematology Analyzer Dilution Protocol

9.7 STCL-EQUIP-002 JA4 Sysmex XS-1000i Hematology Analyzer As Needed Maintenance

9.8 STCL-EQUIP-002 JA5 Sysmex XS-1000i Hematology Analyzer Precision and Calibration Checks

10 REFERENCES

10.1 Sysmex XS-1000i Instructions for Use, Sysmex Corporation, Kobe, Japan, February 2006.

10.2 Sysmex XS-1000i Users Guide, Sysmex Corporation, Kobe, Japan, February 2006.

10.3 Sysmex NE-Series User's Guide, Sysmex Corporation (USA), Inc., Clinical Applications Division, Los Alamitos, CA, 1991 pg. 39.

10.4 Koepke, John. Practical Laboratory Hematology. Churchill Livingstone Inc. 1991. p. 24-25, 36-39.

10.5 NCCLS. Clinical Laboratory Technical Procedure Manuals-Forth Edition; Approved Guideline. (GP2-A4, 2002).

10.6 Sysmex America Inc., Mundelein, IL. Instructions for use of Sysmex SCS-1000™ with Sysmex XE-Series Calibration Program, Rev. 11, 21-Apr-00.

10.7 Sysmex America, Inc., Mundelein, IL. Sysmex e-CHECK Hematology Control insert sheet for Sysmex XE-Series and XS-1000i Analyzers, Rev. 1, 30-Aug-02.

10.8 Sysmex America, Inc., Mundelein, IL. Sysmex e-CHECK Insight™ Overview Guide, Appendix A-Xm Quality Control, Version 1.0a, 14-September-00.

10.9 Sysmex America, Inc., Mundelein, IL. Sysmex Insight™ Overview Guide for Sysmex e-CHECK, Document No: WI-2493A Rev. 06, May 23, 2006.

10.10 Garrity, P., Walters, J., Concepts in New Age Hematology, A Hematology Monograph, Baxter Healthcare Corporation, Scientific Products Division, Hematology Support Services. August 1990

10.11 Cornbleet J. Spurious results from automated hematology cell counters. Laboratory Medicine. 1983:8:509-514.

10.12 CLOROX ULTRA Professional Products Company, Oakland, CA. CLOROX ULTRA product label, 1998.

10.13 Sysmex Reagents of America, Inc. MSDS sheets and reagent product inserts.

10.14 College of American Pathologists (CAP) Hematology and Coagulation Checklist, October 2001.

10.15 Brigden, Malcom L. Cell Counter-Related Abnormalities, Laboratory Medicine, May 1999, Vol. 30, #5, p.325-334.

10.16 Gould, N., Connell, B., Dyer, K., Richmond, T., Performance Evaluation of the Sysmex XE-2100 Automated Hematology Analyzer, Sysmex Journal International, 1999 Vol. 9, No. 2, pp. 120-128.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
04	B. Waters-Pick	• Updated document to make it more specific to the Stem Cell Laboratory instead of applicable to the majority of the general purpose Duke Clinical Laboratories who use the same instrument. • Appendices were removed from the SOP and separated out into individual job aids and then associated with the procedure to make it easier for staff to find the information.

Signature Manifest

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All dates and times are in Eastern Time.

STCL-EQUIP-002 Sysmex XS-1000i Hematology Analyzer for the Stem Cell Laboratory

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Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		25 Mar 2015, 06:42:16 PM	Approved

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Barbara Waters-Pick (WATE02)		25 Mar 2015, 06:42:26 PM	Approved

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John Carpenter (JPC27)		30 Mar 2015, 11:52:14 AM	Approved

Document Release

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