**PURPOSE**

To ensure accurate and reliable test results, automated testing must be performed properly with special attention to method validation, calibration and calibration verification, quality control, and instrument maintenance. This procedure provides instructions regarding operation and maintenance of the Sysmex analyzer.

# PRINCIPLE

The Sysmex XS-1000 is a quantitative automated hematology analyzer for in-vitro diagnostic use for determining 21 hematological parameters. The Sysmex XS-1000 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.

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

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 (NEUT), lymphocytes (LYMPH), monocytes (MONO), eosinophils (EO), and basophils (BASO) by cellular complexity and nucleic acid content. The differential cell placement is then enhanced utilizing Adaptive Cluster Analysis.

# SPECIMEN

1. **Required specimen**
2. Whole blood anticoagulated with a salt of EDTA is preferred.
3. Sodium Citrate may be used when EDTA platelet clumping or platelet satellitism is noted on the EDTA specimen. Use Sodium Citrate results for platelet counts and WBC counts. Multiply instrument PLT and WBC result by 1.11 to correct for anticoagulant dilution.
4. **Specimen volumes required**:
5. Optimal draw is a tube drawn to capacity. The collection tube should be filled to a minimum of one-half full for acceptable results. EXCEPTION: a 2.5 mL EDTA tube filled less than one-half full is unacceptable.
6. A minimum of 500 μL whole blood is required for manual mode analysis.
7. A minimum of 1.0 mL whole blood is required for auto mode analysis (XS-1000*i* with sampler)
8. An EDTA Microtainer® (Becton Dickinson), designed for collection of 500 μL filled above the 250 μL line, is adequate for testing in the open mode. A minimum of 90 μL is required for aspiration using sample tube adapter.
9. **Unacceptable specimens**
10. Clotted samples or those containing clots, fibrin strands, or platelet clumps. All specimens will be checked visually by the operator for obvious clots prior to sampling by the analyzer.
11. Grossly hemolyzed samples.
12. Samples drawn above an IV.
13. **Characteristics that may affect test results**:
    * + 1. lipemia,
        2. icterus,
        3. cold agglutinins,
        4. warm agglutinins,
        5. hemolysis,
        6. electrolyte imbalances,
        7. megakaryocytes
        8. WBC fragments.

E. **Stored Specimen Stability**

1. Stored at 4°C, EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of stability.
2. Sample stability at room temperature is 24 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours; this may be minimized by refrigeration.
3. Allow refrigerated samples to come to room temperature and mix well before analysis.

**NOTE:**

**Do not** place samples on a mechanical rocker. Constant rocking may cause PLT clumping and alter white cell membranes resulting in false interpretive messages.

# II. SUPPLIES & REAGENTS

1. **Supplies**
   * 1. De-ionized water
     2. Lint-free plastic lined lab wipes
     3. Test tubes
     4. CLOROX ULTRA bleach (Use when CELLCLEAN™ is indicated)
     5. Sysmex reagents
     6. Commercial controls:

a. *e*-CHECK, 3 levels (L,N,H) - 4 x 4.5 ml vials, # 199-4004-1

b. *e*-CHECK (XS), 2 levels (N,H) - 5 x 1.5 ml vials, # 199-5002-0

c. *e*-CHECK (XS), 1 level (L) – 5 x 1.5 ml vials, cat. # 199-5001-0

* + 1. Sysmex SCS-1000 whole blood calibrator

1. **Reagents**
2. Four Sysmex reagents and bleach are used on the Sysmex XS-1000*.*
3. All reagents are stored at room temperature and are to be used within the manufacturer's expiration date on each container.
4. Record date received and date opened on container. Record the lot number, expiration date and opened date on XS-1000*i* reagent log.
5. All reagents are azide free, and intended for in vitro diagnostic use only; **do not** ingest.

**Reagent Abbreviation Open Expiration**

Sysmex CELLPACK **EPK** 60 days

Sysmex STROMATOLYSER-4DL **FFD** 60 days

Sysmex STROMATOLYSER-4DS **FFS** 60 days

Sysmex SULFOLYSER **SLS** 60 days

1. **Diluents**

## Sysmex CELLPACK (EPK) is a whole blood diluent for use in the determination of hemoglobin and impedance counting and sizing of blood cells. Sysmex CELLPACK also forms a laminar sheath flow around the diluted sample for hydrodynamic focusing of the RBC and PLT.

### Sysmex CELLPACK Active Ingredients

Sodium Chloride 6.38 g/L

Boric Acid 1.00 g/L

Sodium Tetraborate 0.20 g/L

EDTA-2K 0.20 g/L

### Sysmex CELLPACK Storage

1. Store at a controlled temperature of 5-30o C.
2. **If frozen**, thaw, mix thoroughly, and allow bubbles to disperse before use.
3. Sysmex CELLPACK is clear and colorless. If there are signs of contamination, instability or color change, do not use.

### Sysmex CELLPACK Stability

1. Unopened, 18 months after the date of production marked on the box.
2. Opened, Sysmex CELLPACK is stable for 60 days.

### Sysmex CELLPACK Hazard Risk

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Sysmex CELLPACK does not have ingredients with those characteristics.

**D Lyse Reagents**

## Sysmex STROMATOLYSER-4DL (FFD) is the lysing reagent and diluent for the enumeration of NEUT, LYMPH, MONO, EO, and BASO after eliminating RBC stroma.

* + - 1. **Active Ingredients**

Nonionic surfactant 0.18%

Organic quaternary Ammonium salts 0.08%

* + - 1. **Storage**

1. Store at a controlled temperature of 2-35o C.
2. **If frozen** **do not** use.
3. Sysmex STROMATOLYSER-4DL is a clear, odorless liquid. If there are signs of contamination, instability or color change, do not use.
   * + 1. **Stability**
4. Unopened, 12 months from date of production marked on box.
5. Opened, Sysmex STROMATOLYSER-4DL is stable for 60 days.
   * + 1. **Hazard Risk**

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Sysmex STROMATOLYSER-4DL does not have ingredients with those characteristics.

## II. Sysmex SULFOLYSER (SLS) is the RBC lysing reagent that releases the hemoglobin to be measured by SLS hemoglobin method.

a **Active Ingredients**

Sodium Lauryl Sulfate 1.7 g/L

b **Storage**

1. Store at controlled temperature of 2-30o C.
2. **If frozen**, may form a white cloudy precipitate. Thaw and warm reagent in a 30o Cwater bath to dissolve ingredients completely and mix thoroughly before use.
3. Sysmex SULFOLYSER is a clear, odorless liquid. If there are signs of contamination, instability or color change, **do not** use.

c **Stability**

1. Unopened, 12 months from the date of production marked on the box.
2. Opened, Sysmex SULFOLYSER is stable for 60 days.Lyse Reagents (continued)

d **Health Risk**

The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. Sysmex SULFOLYSER does not have ingredients with those characteristics.

## E Staining Reagents

## Sysmex STROMATOLYSER-4DS (FFS) is used to stain leukocytes in diluted, lysed blood samples for the determination of the 5-part differential including NEUT, LYMPH, MONO, EO and BASO.

a **Active Ingredients**:

Ethylene Glycol 96.9%

Methanol 3.0%

Polymethine dye 0.002%

b **Storage**

1. Store at controlled temperature of 2-35 Co.
2. **If frozen, do not** use.
3. Sysmex STROMATOLYSER -4DS is a blue viscous liquid with a faint odor. If there are signs of contamination, instability or color change, **do not** use.

c **Stability**

1. Unopened, 12 months from the date of production marked on pouch.
2. Opened Sysmex STROMATOLYSER-4DS is stable for 60 days.

d **Health Risk**

Health hazard reflects unusual exposures, via ingestion. This reagent is relatively safe when handled while wearing gloves and when enclosed in the analyzer hydraulic system. Skin contact may cause discoloration. Methanol component is a defatting agent, which may dry and crack the skin. Prolonged and repeated skin contact may cause irritation.

**F Reagent Replacement**

1. When a reagent container is empty, the alarm sounds and the Help Dialog box displays on the IPU. “Replace Container” message with the name and abbreviation for the reagent to be replaced is displayed.
2. Click **[RESET ALARM]** or press **[F1]** to silence the alarm. The Action area of the dialog box displays instructions for reagent replacement.
3. Click **[Execute]** to open Reagent Replacement screen.
4. Once open, the Reagent Replacement screen will display “Replace” next to the reagent to be replaced.
5. Scan the long (lower) barcode label on the container using the handheld bar code reader. Updated information is displayed for lot number, expiration date and volume.
6. Reagent information may also be entered manually.
7. Enter the lot number and expiration date found on the reagent label.
8. Enter the number of days for “Opened Expiration”. **Open dating for all reagents is 60 days.**
9. Open the new reagent container. Using clean technique to avoid contamination, remove the line from the empty container and insert it directly into the new container. Tighten the cap on the new container.
10. Click **[Execute]** to initiate priming.
11. Reagent will be aspirated to satisfy the sensor.
12. The Reagent Log will be updated once priming is complete.
13. To view the Reagent Log, click **[Menu]** or press **[F4],** click on “Controller”icon, and “Reagent Log” icon.

Double click the line for the reagent that was replaced to open the Comment box. A comment (e.g. Tech initials) may be added.

## III. CONTROL and CALIBRATION MATERIALS

**Controls**

Quality Control monitors accuracy and precision of the complete analytical process. Control procedures detect immediate errors, performance over time, and variance in operator performance. Sysmex *e*-CHECK (XS)are whole blood commercial controls for use with the Sysmex XS-1000hematology analyzer. The controls consist of human red and white blood cells with a platelet component suspended in fluid medium. Each vial of Sysmex *e*-CHECK (XS) contains 1.5 mL of control material.

A **Storage**

Store vials as packaged, at 2-8o C.

**Do not** freeze or expose to excessive heat.

B **Stability**

Unopened and properly stored, controls are stable until the expiration date stated on the vial.

1. Open vial stability is 14 days for Sysmex *e*-CHECK (XS) when promptly refrigerated after each use.
2. Record the date on each vial upon opening.
3. Heat or freezing can damage Sysmex *e*-CHECK (XS) 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.
4. If deterioration is suspected, call the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX).

## Calibrator

Sysmex SCS-1000 Calibrator is a secondary whole blood calibrator for use with the Sysmex XS-1000 hematology analyzer. Assay values for primary parameters are traceable to reference methods.The calibrator 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.

A **Storage**

Store vials in the upright position, at 2-8 o C. **Do not** freeze or expose to excessive heat.Sysmex SCS-1000 Hematology Calibrator (continued)

B **Stability**

1. Unopened and properly stored, calibrator is stable until the expiration date stated on the vial.
2. Open vial stability is 4 hours.
3. Storage outside of 2-8o C can damage Sysmex SCS-1000 causing deterioration that risks inaccurate calibration. If deterioration is suspected, call the Sysmex Technical Assistance Center
4. Use of the product at environmental temperatures that exceed 86o F (30 o C) can reduce calibration accuracy.

# IV. CALIBRATION

Initial calibration is performed during installation. 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 service representative upon installation.

The laboratory must verify calibration every six months or on an "as needed" basis to ensure accuracy of the system. Calibration is also required if one or more of the following occur:

* Critical parts are replaced such as manometers, apertures or detector circuit boards.
* Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.
* When advised by Sysmex Field Service Representative.

Calibration verification may include review and documentation of acceptable performance on all three levels of commercial control, and Xm QC data, proficiency testing results and patient control testing results. The operator may calibrate the following parameters: WBC, RBC, HGB, HCT and PLT.

**Before calibration, ensure that the Sysmex XS-1000is both clean and precise.**

1. **Precision Check**
2. Perform routine daily and weekly maintenance on the instrument, and perform a background count to ensure counts are within acceptable limits.
3. Verify that there is sufficient volume of all reagents. Precision and Calibration procedures will be aborted if the Sysmex XS-1000runs out of reagent.
4. Obtain a sample of fresh normal whole blood. **Do not** use commercial controls or calibrators for precision. The blood donor specimen should:
5. be free from medication, and interfering substances such as lipemia, icterus, platelet clumps, hemolysis, etc.
6. have morphologically and numerically normal CBC.
7. be drawn in EDTA anticoagulant tube using proper collection technique.
8. be a minimum of 2 mL of sample.
9. On the IPU, click **[Menu]** or press **[F4]**.
10. Click on the “Controller” icon in the Menu window.
11. Double click on the “Precision Check” icon on the Controller menu.
12. Attach appropriate tube adapter to the sample position.
13. Place the well-mixed sample tube in the tube position.
14. 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.
15. 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]**.
16. If all results are within Precision Limits, click **[OK]** on the Precision Check screen to save the data and close the Precision Check window.
17. 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].
18. **Calibration Check**
19. Prepare the Sysmex SCS-1000 calibrator according to the product insert.
20. Click **[Menu]** or press **[F4]**.
21. Click the “Controller” icon on the Main menu window.
22. Double-click the “Calibrator Calibration” icon on the Controller menu.
23. 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.
24. Attach the appropriate sample tube adapter.
25. 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.
26. 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.
27. 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-SeriesInstructions for Use manual.
28. 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.
29. Click [OK] to execute the calibration or [Cancel] if calibration is not desired or necessary. The display returns to the Controller menu.IV. CALIBRATION (continued)
30. 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.
31. Print the Calibration History.
32. Click **[Menu]** or press **[F4]**.
33. Click the “Controller” icon.
34. Click the “Calibration History” icon.
35. Click on the calibration date in the Calibration History list.
36. 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]**.
37. Following calibration, analyze commercial controls. Adjust target values if necessary

# V. RUNNING QUALITY CONTROL

A. **Instructions for use**.

1. Remove Sysmex *e*-CHECK (XS) vials from refrigerator and allow them to come to room temperature (18-25o C), for approximately 15 minutes.
2. Mix vials by gentle end to end inversion until the cell button in the bottom of the vial is completely suspended.

B. **Frequency of Controls Use and Review**

1. 3 levels of controls must be run every 8 hours.
2. The supervisor reviews commercial control and Xm charts monthly.

C. **Entering Lot Information for a New Lot of Controls**

1. Click **[QC Files]** or press **[F5]**.
2. Click on file number (1-20).
3. Click **[Input]** or press **[F9]**. The QC dialog box displays.
4. Click on **[▼]** beside “Material” to select the control level.
5. Click in the field for “LOT NO.”. Using the keyboard, enter the lot number from the vial or assay sheet.
6. Click on **[▼]** beside the “Exp. Day” to display the calendar. Click on the expiration date in the calendar to display it in the field.
7. Click **[OK]** to update the lot information.
8. Repeat steps 2-7 to enter lot information for the other levels of control.
9. If reagent is a new lot number, record on form **HEM50-001-Form B1**. Verify performance of new lot by acceptable background count, controls, and/or reproducibility

D. **QC Analysis**

1. QC analysis in the **Manual** mode. (XS-1000*i*)
2. Click **[Manual]** or press **[F2]**. The Manual Sample No. dialog box opens.
3. Enter the lot number using one of the following methods:

* Use the handheld barcode reader to scan the bar code from the vial.
* Use the keyboard to type the lot number.

**Note: *“****QC” must be upper case followed by a hyphen.*

* Click the **[QC]** button on the Manual Sample No. dialog box. Click on the QC level to be analyzed. Click on **[OK]**.

1. Press the Open/Close switch to open the sample position.
2. Attach the appropriate tube adapter for the vial to be analyzed.
3. Place the well-mixed vial in the adapter and press the **“Start”** switch on the Main Unit.
4. The QC results display when analysis is complete. Results which are outside of acceptable limits display with red background. Click **[ACCEPT]** to accept the results, or **[CANCEL]** to reject.
5. Follow steps a-f to analyze other levels of controls.
6. QC analysis in the **Manual** mode. (XS-1000*i* with Sampler)
   1. Click **[Manual]** or press **[F2]**. The Manual Sample No. dialog box opens.
7. Enter the lot number by one of the following methods:

* Use the handheld barcode reader to scan the barcode from the vial.
* Use the keyboard to type the lot number.

**Note: *“****QC” must be upper case followed by a hyphen.*

* + - Click the **[QC]** button on the Manual Sample No. dialog box. Click on the QC level to be analyzed. Click on **[OK]**.

1. Attach the appropriate tube adapter for the vial to be analyzed.
2. Place the well-mixed vial in the adapter and press the **“Start”** switch on the right side inside the sampler.
3. The QC results display when analysis is complete. Results which are outside of acceptable limits display with red background. Click **[ACCEPT]** to accept the results, or **[CANCEL]** to reject.

f Follow steps a-e to analyze other levels of controls.

1. QC analysis in the **Sampler** mode with **Barcodes**. (XS-1000*i* with sampler)
2. Place a Sysmex rack in the rack position of the Sampler with the notch on the rack to the right.
3. Place the well-mixed control vials in positions 8, 9, 10 of the Sysmex rack.
4. Attach the appropriate sample tube adapter.
5. Close the Sampler cover.
6. Click **[Sampler]** or press **[F3]**.
7. 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. Press the sampler **Start** switch on the left side of the Main Unit.
9. A dialog box displays when analysis is complete.
10. Document daily QC on **HEM50-005 Form A**

E. **Review QC**

* + - 1. Radar Charts
  1. On the IPU, click **[QC Files]** or press **[F5]**.
  2. Click on the file to be reviewed.
  3. The Radar Chart displays beside the selected file.
  4. Results of the most recent analysis display in blue. Date and time of analysis are displayed in the Analysis Date column.
  5. Results outside of acceptable limits are displayed with a red “X” and the parameter name is displayed with a red background.
     + 1. L-J Charts
       2. On the IPU, click **[QC Files]** or press **[F5]**.
       3. Double click on the file to be reviewed. The Levy-Jennings chart will be displayed.
       4. 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.
       5. Scroll through the screens to view all parameters by using the scroll bar on the right of the screen or press the down arrow.

Verify that all parameters fall within established limits or within the package assay range. Contact the Sysmex Technical Assistance Center to investigate any suspected control product failure.

F. **Auto-Set Targets**

Parallel test new controls by analyzing each level of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated, auto-set the targets.

1. On the IPU, click **[QC Files]** or press **[F5]**.
2. Double-click on the appropriate file number (1-20) to open the L-J chart.
3. Set the range of data for target calculation by clicking on the green cursor and dragging to the left to include all points to be used in calculation, or press **[Ctrl]** and **[A]** to select all data.
4. Click **[Input]** or press **[F9]**.
5. Click on RBC in the Target/Limit window and click and drag to include all parameters.

G. **Reproducibility**

A patient sample is run to verify instrument reproducibility each day. After the morning run, select a normal specimen with adequate volume. Sample is run approximately every four hours in a reproducibility file.

1. Go to QC files (F5)
2. Select ‘Other’.
3. Run sample just as a QC sample.
4. Review data. Reproducibility limits are as follows:

**Parameter % CV**

WBC ≤ 2.5

RBC ≤ 2.0

Hb ≤ 1.5

PLT ≤ 5.0

MPV ≤ 3.0

4. If %CV exceeds established limits, review results for obvious outliers, indicating incomplete aspiration, count period vote-out, or another cause of invalid results. Reject result and repeat.

5. Print reproducibility file after 24 hours (prior to next day’s first reproducibility run).

a. Go to Report (F7)

b. Select ‘Ledger’ results will print

c. File in QC binder under ‘Reproducibility’ section

**VI. OPERATING PROCEDURE**

A. Start-Up Procedure

1. Check pneumatic trap for fluid and drain if necessary.
2. Check reagent boxes for sufficient run volume.
3. Check printer paper supply.
4. Power Up Sequence
5. ***Press power switch on Information Processing Unit (IPU). IPU log on must be done before powering up the Main Unit.***
6. ***Sysmex XS-1000 program log-on box displays. Log on the IPU with User Name (XS) and press*** *[ENTER]****. No password is required. Substitute your user name and password if they have been assigned.***
7. Press the power switch on right side of the Main Unit.
8. The instrument automatically performs self-check on the:

Microprocessor Mechanical parts

Temperatures Background counts

|  |  |
| --- | --- |
| Sysmex XS-1000*i* Acceptable Background Counts | |
| **Parameters** | **Acceptable Limit** |
| RBC | 0.02 x 106/ μL |
| HGB | 0.1 g/dL |
| PLT | 10 x 103/ μL |
| WBC - C | 0.1 x 103/ μL |
| WBC - D | 0.1 x 103/ μL |

1. Press the power switch on the printer.
2. Analyze Quality Control.

B. Patient Sample Processing

1. Manual Mode – (20 μL aspirated sample volume) minimum of 500 μL in tube or 90 μL in a micro-sample container

1. On the IPU, click **[Manual]** or press **[F2]**.
2. Enter the specimen number (alpha or numeric characters) using the keyboard or using the handheld bar code reader.
3. Click on CBC or CBC+Diff if this information is not being provided by the Host Computer.
4. Click **[OK]**.
5. Attach appropriate sample tube adapter.
6. Mix the patient sample 10 times by end-to-end inversion.
7. Place sample in sample tube adapter. It is not necessary to remove the cap except when using non-pierceable micro-sample containers.
8. Press **Start** switch. (Located above the sample tube position on the Main Unit of the XS-1000*i* without Sampler; inside the sampler cover on the XS-1000*i* with Sampler.)
9. When Ready LED is lit green, repeat steps a-i for each additional sample.

B. Patient Sample Processing (continued)

2. Sampler Mode with Bar Codes – XS-1000*i* with Sampler

(20 μL aspirated sample volume). A minimum of 1.0 cc of blood is required in the tube for the sampler mode.

1. Place a Sysmex rack in a rack position of the Sampler with the notch on the rack to the right.
2. Place up to 2 racks at one time (up to 20 samples).
3. Place bar coded specimens in the rack. Ensure that labels are smooth with no loose edges.
4. Attach the appropriate sample tube adapter.
5. Close the Sampler cover.
6. On the IPU, click **[Sampler]** or press **[F3]**. The Sample number dialog box displays.
7. Click on the starting position for the rack and tube position in which the tubes have been placed. Press **[OK]**.
8. Press sampler **Start** switch on the left side of the Main Unit.
9. The Sysmex XS-1000*i* automatically mixes the sample 10 times, aspirates, and analyzes the sample according to the bar code discrete order if bidirectional interface is used. Results print as they are completed if auto-output is selected.
10. A dialog box displays when analysis is complete.

B. Patient Sample Processing (continued)

3. Capillary Mode (67 μL aspirated volume of 1:7 diluted sample)

1. Prepare a 1:7 dilution by pipetting 120 μL of CELLPACK into a tube, then adding 20 μL of whole blood.
2. On the IPU, click **[Manual]** or press **[F2]**.
3. Enter the specimen number (alpha or numeric characters) using the keyboard or using the handheld bar code reader.
4. Click on CBC or CBC+Diff if this information is not being provided by the Host Computer.
5. Click on the “Yes” radio button to select Capillary Mode.
6. Click **[OK]**.
7. Attach the appropriate sample tube adapter.
8. Place the well-mixed dilution in the adapter.
9. Press the **Start** switch. (Located above the sample tube position on the Main Unit of the XS-1000*i* without Sampler; inside the sampler cover on the XS-1000*i* with Sampler.)
10. The analyzer will multiply all parameters by 7, including the Diff parameters, and display the results. **Do not** analyze an undiluted sample.
11. Return the mode to “Manual”, by repeating steps b-f and selecting the “NO” radio button for Capillary Mode.
    1. **Shut Down** – Perform every 24 hours

**Cleans the detector and dilution lines**

1. Click **[Menu]** or press **[F4]**.
2. Double click on the “Shutdown” icon.
3. After 2 minutes, a dialog box on the IPU displays “Please power off the analyzer”.

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

1. Power off the Sysmex XS Main Unit.
2. To power off the IPU, click **[File]** from the menu bar, then click **[Exit]**.
3. Dialog box displays ”Do you really want to Log off?” Click **[OK]**.
4. Click on **Start** button at the bottom of Windows desktop.
5. Click **[Shut Down]**.

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

1. The system displays: “Please wait while the system writes unsaved data to the disk”.
2. Record on Maintenance Log.

11. Print out the background check daily:

* + - * 1. Click Explorer tab (F7)
        2. Double click on Background check
        3. Click ‘Report’
        4. Select ‘Report’ note: Make sure ‘Last 20’ tab is de-selected
        5. File report in QC binder

# VII. MAINTENANCE

This section includes written procedures for performing monthly and 30,000 cycle maintenance. Refer to Sysmex *XS-Series* *Instructions for Use* manual, Chapter 9 for detailed, illustrated procedures. All maintenance is documented on **HEM50-005 Form A**

**WARNING for All Maintenance:**

CLOROX ULTRA contains a strong oxidizing agent. Causes substantial but temporary eye injury. May irritate skin. May cause nausea and vomiting if ingested. Exposure to vapor or mist may irritate nose, throat and lungs. If contact with eyes, flush with copious amounts of water. Also, potential biohazard exposure when performing maintenance on the Sysmex XS-1000*i*.

**Recommended:**

Wear gloves, lab coat and safety glasses for protection.

**\*\*Important Note For All Maintenance**

## CLOROX ULTRA

## CLOROX ULTRA bleach is recommended for use in cleaning of the Sysmex XS-1000 analyzer whenever CELLCLEAN is indicated.

CLOROX ULTRA Ingredients

Sodium Hypochlorite 6.0%

CLOROX ULTRA Storage

Stable under normal use and storage conditions

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

**One Liter of 5% from 6% Sodium Hypochlorite:**

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

so (6%) x (Vol 1) = (5.00%) x ( 1 liter, 1000 mL)

V1 = 5.00/6 x 1000 mL

V1 = 833 mL bleach and 167 mL of distilled water will make one liter of 5% Sodium Hypochlorite solution. Store stock 5% bleach in a dark place to prevent solution degradation from exposure to light.

**A. Monthly:**

* + - 1. **Rinse Sequence** – **to be performed monthly or every 1200 cycles. Cleans the optical detector block**

1. Click **[Menu]** or press **[F4]**.
2. Click “Controller” icon on the menu screen.
3. Click “Maintenance” icon. The maintenance screen displays.
4. Click on “Monthly Rinse”. The Monthly Rinse dialog box displays.
5. Attach the appropriate sample tube adapter.
6. Place a tube of 5% Sodium hypochlorite solution (CELLCLEAN) in the tube adapter.
7. Press the **Start** switch. (Located above the sample tube position on the Main Unit of the XS-1000*i* without Sampler; inside the sampler cover on the XS-1000*i* with Sampler) to initiate the cleaning.
8. Record on Maintenance Log.
9. The Power Off dialog box displays when the process is complete.
10. Press [Restart] to resume operation or power off the instrument.

## B. As-needed Maintenance

**1. Waste Chamber Cleaning**

1. Click **[Menu]** or press **[F4]**.
2. Click “Controller” icon on the menu screen.
3. Click “Maintenance” icon. The maintenance screen displays.
4. Click on “Rinse Waste”. The Rinse Waste dialog box displays.
5. Attach the appropriate sample tube adapter.
6. Place a tube of 5% Sodium Hypochlorite solution (CELLCLEAN) in the tube adapter.
7. Press the **Start** switch. (Located above the sample tube position on the Main Unit of the XS-1000*i* without Sampler; inside the sampler cover on the XS-1000*i* with Sampler) to initiate the cleaning.
8. The dialog box closes when the sequence is complete.
9. Record on Maintenance Log.

**2. Perform Rinse Flow Cell Cleaning**

Perform if Flow Cell in optical detector is suspected to be dirty.

1. Click **[Menu]** or press **F4**.
2. Click “Controller” icon on the menu screen.
3. Click “Maintenance” icon. The maintenance screen displays.
4. Click on “Rinse Flow Cell”. The Rinse Flow Cell dialog box displays.
5. Attach the appropriate tube adapter.
6. Place a tube of 5% Sodium Hypochlorite solution (CELLCLEAN) in the tube adapter.
7. Press the **Start** switch (Located above the sample tube position on the Main Unit of the XS-1000*i* without Sampler; inside the sampler cover on the XS-1000*i* with Sampler) to initiate the cleaning.
8. The dialog box closes when the sequence is complete
9. Record on Maintenance Log.

**3. Perform Air Bubble Removal for Flow Cell**

Perform if air bubbles in Flow Cell create abnormal aggregate pattern on scattergram.

1. Click **[Menu]** or press **[F4]**.
2. Click “Controller” icon on the Menu screen.
3. Click “Maintenance” icon. The maintenance screen displays.
4. Click “Remove Air Bubbles”. The sequence begins.
5. The dialog box closes when the sequence is complete.
6. Record on Maintenance Log.
   * 1. **Remove RBC Clogs with Remove Clog Sequence**

Perform when “RBC Clog Error,” “RBC Bubble Error”, or “RBC/PLT Sampling Error” message displays.

1. When error message is displayed, the HELP dialog box displays the error. Click on the error.
2. Click **[OK]** to begin Clog Removal Sequence.

Alternate Method for Performing Clog Removal

(when no error is displayed)

c. Click [Menu] or press [F4].

1. Click “Controller” icon on the Menu screen.
2. Click “Maintenance” icon. The Maintenance screen displays.
3. Click on “Remove Clogs” icon and the sequence begins.

**VIII. CALCULATIONS**

1. If making a 1:7 dilution of patient specimen and **NOT** running in the capillary mode, multiply measured parameters by 7; recalculate indices.
2. If correcting the HGB or HCT due to interfering substances recalculate and correct the affected indices:

MCHC = HGB/HCT x 100

MCH = HGB/RBC x 10

MCV = HCT/RBC x 10

1. If a sodium citrate tube is used for EDTA induced platelet clumping, multiply the citrate platelet count by 1.11 to correct for anticoagulant dilution.

# IX. EXPECTED VALUES

The following are normal values for the adult population:

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Units** | **Reference Range** |
| WBC | x103 cells/mcL | 4.0 - 11.0 |
| RBC | x 106 cells/mcL | 4.70 ‑ 6.10 (M)  4.10 5.00 (F) |
| HGB | g/dL | 14.0 - 18.0 (M)  12.0 - 16.0 (F) |
| HCT | % | 39.0 - 50.0 (M)  35.0 - 43.0 (F) |
| MCV | fl | 81.0 - 96.0 |
| MCH | pg | 27.0 - 33.0 |
| MCHC | g/dL | 32.0 - 36.0 |
| RDW | % | 11.4 - 14.9 |
| Plt | x103 cells/mcL | 140 – 400 |
| MPV | fL | 7.4 - 10.4 |
| NE | % | 44.0 - 79.0 |
| LY | % | 11. 0 - 40.0 |
| MO | % | 1.9 -11.4 |
| EO | % | 0.0 - 5.2 |
| BA | % | 0.0 - 1.3 |
| NE | x103/mcL | 1.7 - 8.4 |
| LY | x103/mcL | 0.4 - 4.2 |
| MO | x103/mcL | 0.0 - 1.2 |
| EO | x103/mcL | 0.0 - 0.6 |
| BA | x103/mcL | 0.0 - 0.1 |

**X. CRITICAL VALUES**

The following are critical values and are phoned to appropriate care-giver and documented in LIS.

**Parameter Low Critical High Critical**

**WBC:**

Birth to one month ≤ 2,000/mcL ≥ 35,000/mcL

All other ages ≤ 2,000/mcL ≥ 100,000/mcL

**Hemoglobin:**

Birth to one month ≤ 13.0 g/dL ≥ 28.0 g/dL

All other ages ≤ 6.0/g/dL ≥ 18.0 g/dL (F)

≤ 20.0 g/dL (M)

**Platelet:** ≤ 20,000/mcL ≥ 900,000/mcL

See Procedure HEM20-005 for more information.

**XI**. **REPORTING RESULTS**

**A.** Review patient specimens for presence of instrument-generated and/or laboratory-defined suspect flags, codes, or messages. Appropriate action is taken prior to releasing patient results.

1. If no flags that warrant further action are present and there are no delta failures, patient results are verified in LIS.
2. Critical results are called to the floor and documented in LIS prior to verification of results.
3. Delta failures are investigated prior to verification of results, especially those for MCV or Hgb. See Procedure HEM20-008 for more information.

a. All MCV delta failures are investigated to confirm specimen is not mislabeled. Confirm blood type either by historical record or by pulling a previous sample for blood typing. **Results are NOT released without verification of sample.**

**B.** The following flags, codes and/or messages are investigated prior to verification of results:

1. MCHC > 37.0
2. Failure of “Rule of three”: Hgb x 3 = Hct ± 3
3. Platelet flags, including “giant platelets”, “platelet clumps” or a no-fit histogram.

**C.** The following flags, codes, and/or messages warrant further action, such as a manual differential or scan (see HEM50-002):

1. Variant lymph (Atypical, Abnormal)
2. Blasts
3. Immature Grans, Left shift
4. RBC Agglutination or Lyse Resistance
5. NRBC flag
6. Turbidity/HGB interference
7. HGB Defect
8. Iron Deficiency

**D.** Certain numeric values on WBC count and/or diff parameters warrant a manual diff (see HEM50-002).

**E.** Certain numeric values on the platelet count warrant a scan or manual platelet count (see HEM50-002).

**F.** RDW result ≥ 25.0% requires scan for RBC morphology once every 72 hours.

**XII. PROCEDURE NOTES**

**A.** Patient specimens are repeated prior to reporting, as follows:

1. WBC: Repeat first time when ≤ 2.0 x103 cells/mcL or ≥ 30.0 x103 cells/mcL, or ≤ 1.0 x103 cells/mcL or ≥ 60.0 x103 cells/mcL if previously done.
2. Hgb: Repeat first time when ≤ 7.0 g/dL or ≥ 16.0 g/dL(F), or ≥ 18.0 g/dL (M), or ≤ 5.0 g/dL if previously done.
3. Platelet: Repeat ≤ 50 x103 cells/mcL or ≥ 900 x103 cells/mcL (first time or previous).

**B.** Patient specimens exceed instrument linearity and require a dilution as follows:

1. WBC ≥ 400.0 x103/μL
2. Hgb ≥ 25.0 g/dL
3. Platelet ≥ 5,000 x103/μL

**C.** SYSMEX XS does not correct WBC for presence of nucleated RBCs. Manual correction is as follows:

Corrected WBC = Instrument WBC x 100\_\_\_

100 + # nRBCs per 100 WBCs

Correction is required when the number of nRBCs is > 5 per 100 WBCs.

1. Megakaryocytes: When megakaryocytes are present, perform a WBC and PLT estimate.
2. Capillary Analysis:
3. Use when insufficient patient sample is available for aspiration (<500 μL) or a sample has a parameter above the linearity limits of the analyzer.
4. Use if there are marked changes in plasma constituents, (i.e. very low sodium or very high glucose), prepare a 1:7 dilution and allow to equilibrate before analysis.
5. Analysis of the specimen on Sysmex XS-1000 is recommended before removing the cap to make a smear.
6. **Do not** place samples on a mechanical rocker. Excessive mixing may induce platelet clumping and alter white cell membranes resulting in false interpretive messages.

**XIII. LIMITATIONS OF PROCEDURE**

**A. Cold Agglutinin:**

Cold agglutinins produce spurious macrocytosis, elevated MCH's, MCHC's, falsely decreased RBC counts and HCT's. Rare Warm agglutinins produce the same spurious results as a cold agglutinin.

1. When a cold agglutinin is present, clumps of RBCs form as the temperature falls below 25oC. RBC clumps are counted as single large cells, falsely lowering the RBC count and affecting the RBC indices.
2. Indicators are: H& H fail the “Rule of three”, MCHC > 37.0, markedly increased MCV.
3. Follow procedure HEM10-008 to resolve.
4. Confirm presence of RBC agglutinins on peripheral smear made prior to warming tube.
   1. **Lipemic Specimens:**
5. Lipemia falsely elevates the HGB and MCHC. Perform a plasma replacement,

plasma blank procedure or make 1:7 dilution with CELLPACK.

1. Indicators are: H&H fails the “Rule of three”, MCHC > 37.0.
2. Follow procedure HEM10-006 to resolve.

**C. Platelet Clumps:**

Giant Platelets and Platelet clumping and/or "platelet satellitism" can occur in specimens collected in EDTA. This may falsely elevate the WBC and falsely decrease the platelet count. Recollect the specimen in Sodium Citrate anticoagulant and multiply by 1.11 dilution factor.

1. Clumped platelets are counted by the SYSMEX XS as single large cells, lowering the platelet count and affecting the MPV.
2. Instrument may give “platelet clumps” or “giant platelets” flag; instrument count may not match platelet estimate from peripheral smear.
3. Examine platelet histogram for abnormalities.
4. Follow procedure HEM10-002 to resolve, including performing platelet count from blue-top tube.

**D. Other Issues Affecting Platelet & WBC Counts:**

1. Micro-spherocytes may affect WBC and/or platelet counts.
2. Follow procedure HEM10-005 to resolve.

**E. Other Interferences:**

1. Extremely elevated WBC counts may cause turbidity, falsely increasing the Hgb.
2. Abnormal proteins (such as with multiple myeloma or Waldenstrom’s macro-globulinemia) may falsely increase the WBC count.
3. Extremely icteric samples may falsely elevate the Hgb and related RBC indices.
4. Extremely elevated glucose levels may cause the RBCs to swell, resulting in a falsely increased MCV.
5. Specimens must be free of clots and fibrin strands.
6. Marked changes in plasma constituents (e.g., low sodium, extremely elevated glucose) may cause cells to swell or shrink. The blood to anticoagulant ratio is important.
7. Red cell fragments, microcytic RBC's or white cell cytoplasmic fragments may interfere with automated platelet counts.
8. Severely hemolyzed samples (in vitro) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
9. Severely Icteric samples may falsely elevate the HGB value and related indices. Make a 1:7 dilution with Sysmex CELLPACK.
10. Rocking specimen excessively may affect the WBC differential.

**XIV. QUALITY ASSURANCE**

**A.** Results are submitted and reviewed by the Lead Technologist for each lot number of control to Sysmex’s IQAP Program. A printed report provides a complete statistical analysis of the Sysmex XS’s performance and compares its performance to a peer group.

**B.** Mode-to-mode comparison is performed at least semi-annually to ensure both modes are yielding comparable results. Three patient specimens are run in both the Auto (primary) and Manual (secondary) modes and the difference for each parameter is evaluated for acceptability. Results are recorded on form **HEM50-001-EP Form B**.

**C.** The Sysmex XS 1000 and Sysmex XN 1000 (at EMCP) are correlated at least every six months to ensure patient results obtained on one are consistent with results from the other. Refer to Procedure HEM20-011 for specific procedure.

* 1. CLOROX ULTRA, a filtered bleach, is recommended for use in cleaning. If CLOROX ULTRA is not available generic bleach may be used, but must be 5% Sodium Hypochorite concentration and be free of particles that may cause background contamination when used on the analyzer. CLOROX ULTRA must be diluted from 6% by volume (straight from the bottle) to 5% before preparing further dilutions recommended for maintenance.

# XV. Sysmex XS-1000MANUFACTURER STATED LINEARITY:

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Range** | **Units** |
| WBC | 0-400.0 | x103/μL |
| RBC | 0-8.00 | x106/μL |
| HGB | 0-25.0 | g/dL |
| HCT | 0-60.0 | % |
| PLT | 0-5000 | x103/μL |

1. Parameters that exceed these limits are flagged with @ beside the result. The sample must be diluted, rerun and multiplied by the dilution factor, or dilute 1:7 and use the capillary mode.

2. Note the use of dilution for linearity on the patient report.

**XVI. TROUBLESHOOTING**

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

**WARNING:**

CLOROX ULTRA contains a strong oxidizing agent. Causes substantial but temporary eye injury. May irritate skin. May cause nausea and vomiting if ingested. Exposure to vapor or mist may irritate nose, throat and lungs.

**Recommended:**

Wear gloves, a lab coat and safety glasses for protection

# XVII. REFERENCES

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**Approval Signatures:**

|  |  |  |
| --- | --- | --- |
| Date | **Printed Name** | **Signature** |
|  | Vanessa Rawlings, MHA, MT  Elkins Park Laboratory Supervisor |  |
|  | Vivian Arguello, MD  Section Director of Hematology |  |
|  | Nancy A. Young, M.D.  Medical Director |  |

## History Review

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| **Date**  **Reviewed** | **Reviewed By** | **Revisions** |
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