|  |  |
| --- | --- |
| Policy Statement | Core Laboratory Personnel are responsible for insuring the specimen submitted for testing is acceptable and the procedure for performing this assay is not violated. |
| Purpose | This procedure provides technical instruction for acceptable performance of the “Complete Blood Count of Whole Blood” on the Sysmex XE-Series” analyzer. |
| Scope | This procedure applies to testing personnel authorized to perform testing using the Sysmex  XE-5000 analyzer. |
| **Responsibility** | All authorized personnel are responsible for following procedural guidelines and insuring good laboratory practice is followed. |
| **Related Documents** | Sysmex Operators XE-5000 Main Manual  Sysmex Operators XE-5000 IPU Manual  Sysmex Training Manual |

**COMPLETE BLOOD COUNT OF WHOLE BLOOD**

**ON THE SYSMEX® XE-5000**

# PRINCIPLE

The Sysmex XE-5000 is a quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 61 diagnostic parameters. Examination of the numerical and/or morphological findings of the complete blood count are useful in the diagnosis of disease states, such as anemias, leukemias, allergic reactions, viral, bacterial, and parasitic infections.

The XE-5000 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, differential, reticulocytes (RET) and nucleated red blood cells (NRBC) are all evaluated using flow cytometry with a semiconductor laser exploiting the differences in cell size, complexity and RNA/DNA content. WBC and basophils (BASO) are treated with an acidic lyse that lyses RBC and WBC, but not BASO. The remaining WBC nuclei and intact BASO are differentiated by cell size and internal cell structure. The WBC differential channel classifies lymphocytes (LYMPH), monocytes (MONO), eosinophils (EO), granulocytes, and immature granulocytes (IG) by cellular complexity and nucleic acid content. The differential

cell placement is then enhanced using Adaptive Cluster Analysis. Reticulocytes are separated from mature RBC and PLT by size and RNA content. NRBC are separated from WBC based on nuclear size after lysing and DNA/RNA staining.

The Immature Information channel (IMI) cytochemically differentiates immature myeloid cells from mature granulocytes based on membrane lipid content, and direct current and radio frequency technologies.

# SPECIMEN

1. Required specimen
2. Whole blood anticoagulated with potassium EDTA is preferred.
3. Sodium Citrate may be used when EDTA platelet clumping or platelet satelitism is noted on the EDTA specimen. See CORE 6520 R Clumpled or Giant Platelets and Platelet Satellitosis.
4. Specimen volumes required
5. Optimal draw is a tube drawn to capacity.
6. A minimum of 1 mL of whole blood is required for automode analysis.
7. An EDTA micro-container filled above the 250 μL line is adequate for testing in the manual mode.
8. Unacceptable specimens including those listed below must be redrawn:
9. Clotted samples or those containing clots or fibrin strands. All specimens will be checked visually for obvious clots prior to sampling by the analyzer.
10. Grossly hemolyzed samples
11. Samples drawn above an IV line
12. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins.
13. Stored Specimen Stability
14. Stored at 4-8°C, EDTA blood samples with normal results may be analyzed up to 24 hours without significant loss of differential stability.
15. Sample stability at room temperature is 24 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours, which may be minimized by refrigeration.
16. Allow refrigerated samples to come to room temperature and mix well before analysis.
17. **Do not** place CBC and Diff samples on a mechanical rocker. Constant rocking may cause PLT clumping and alter white cell membranes, resulting in false interpretive messages.
18. **OPERATING PROCEDURE**
19. Start-Up Procedure
20. Check physical status.
21. Check pneumatic trap chamber. (Refer to Section 9.2 of the XE-5000 Instructions for Use for detailed information).
22. Check reagent boxes for sufficient run volume.
23. Check printer paper supply.
24. Power-Up Sequence
25. Press power switch on IPU – Information Processing Unit. Must log on before powering up the Main Unit.
26. Log-on the IPU
27. XE-5000 program log-on box appears. Type User Name HEME and press [ENTER].
28. Press the power switch on Main Unit. The Pneumatic Unit is controlled by the Main Unit, so Pneumatic Unit power is left on. The instrument automatically performs self check on the:

Microprocessor Mechanical parts

Temperatures Background counts

1. Press the power switch on the printer.
2. When the “Logon Name and Password” screen displays, log on to the Main Unit.
3. Press [NUM/ALPH] on the Main Unit to display alpha characters (if alpha characters are used for Logon Name).
4. Press the appropriate keys HEME on the Main Unit keypad to enter the Logon Name.
5. Press [ENTER] for the password.
6. Check background check on Start-up log (See chart of acceptable limits below).

|  |  |
| --- | --- |
| **XE-5000 Acceptable Background Counts** | |
| **Parameters** | **Acceptable Limit** |
| WBC | 0.1 x 103/ μL |
| Diff -WBC | 0.2 x 103/ μL |
| IMI-Total | 0.3 x 103/ μL |
| IMI# | 0.005 x 103/ μL |
| NRBC-WBC | 0.2 x 103/ μL |
| RBC | 0.02 x 106/ μL |
| HGB | 0.1 g/dL |
| PLT | 5 x 103/ μL |
| PLT-O | 10 x 103/ μL |

1. Check pneumatic unit readings.

Vacuum (-0.05 MPa or higher) Pressure (0.25 + 0.03 MPa)

1. Analyze Quality Control. See section IV Quality Control
2. Patient Sample Processing
3. SAMPLER (AUTO) MODE WITH BARCODES **(200 μL sample volume)**
4. Place specimens in a rack with barcodes **facing the front of the rack**. Ensure that labels are smooth with no loose edges.
5. Load up to 10 racks at one time (100 samples). A new rack may be added to the right rack pool at any time.
6. Press **[SAMPLER]** on the Main Unit keypad.
7. Press **[START]** from the Function menu or press **[SAMPLER]** again to begin analysis.
8. The XE-5000 automatically mixes the sample 10 times, aspirates, and analyzes the sample according to the barcode discrete order. Results will auto validate if there are no analytical errors as they are completed.
9. MANUAL MODE **(130 μL sample volume)**
10. Press **[MANUAL]** on the XE Main Unit keypad.

**NOTE**: *If sample is barcoded, auto analysis is in place and Mode on Main Unit already displays MANUAL, it is only necessary to wand in the Sample ID from the barcode label using the handheld wand – proceed to step “f” after wanding in Sample ID.*

1. Enter the specimen number (up to 15 alpha/numeric characters), using the Main Unit keypad or handheld barcode wand.
2. Press **[▼]** to select the Manual Mode.
3. Press **[▼]** to select the Discrete tests to be performed on the sample.
4. Press **[ENTER]**.
5. Mix the patient sample. Uncap the tube.

**WARNING**: Potential biohazard exposure when handling open patient specimens. Follow Standard precautions outlined by laboratory safety guidelines.

**Recommended:** Wear gloves, a lab coat, and safety glasses. Use plastic lined gauze when opening.

1. Place sample under the aspiration pipette so that the tip of the pipette is at the bottom of the sample.
2. Press **[Start]** switch. Remove the sample when 2 beeps sound, or the green Ready LED stops blinking. Patient results will print as samples are completed, if auto-output is selected.
3. When Ready LED is on, repeat steps a-h for each additional sample.
4. SHUT DOWN – Performed every 24 hours or 500 cycles.

**NOTE: Shutdown will be performed during the second shift (dayshift). One analyzer will be set on single mode while performing shutdown. This setting will direct the LASC to send all samples to the alternate analyzer.**

1. Press **[SHUTDOWN]** on Main Unit keypad.
2. Hold 5 mL of 5% filtered Sodium Hypochlorite (Clorox bleach) up to the manual aspiration pipette. (Refer to instructions in Maintenance Section for mixing a 5% bleach concentration from 6% Clorox).
3. Press manual **Start** switch. 4 mL of bleach will be aspirated.
4. When beeping stops and “Ready” LED turns off, remove bleach. Bleach cycles through detector chamber and dilution lines.
5. After about 15 minutes, Main Unit displays “Turn POWER Off”. Press the Main unit ON/OFF switch.

**Note**: *To continue analysis, select* ***“Restart”*** *from XE-5000 Shutdown screen. After auto-rinse and background check is completed, XE-5000 is “Ready”.*

1. To Power off the IPU, click on **[FILE]** and **[EXIT]**.
2. Dialog box displays ”Do you really want to exit”. Click **[YES]**.
3. Click **[START]** at the bottom of Windows desktop.
4. Click **[Shut Down]**.
5. In the Shutdown dialog window, select “Shutdown”, and click **[OK]**.
6. The IPU shuts off automatically when the process is complete.
7. Record on Maintenance Log.

# QUALITY CONTROL

## COMMERCIAL CONTROL MATERIAL

***e*-CHECK(XE)** manufactured by Streck, available as a tri-level package or as 3 levels packaged individually, is a whole blood commercial control for use with the Sysmex XE-5000 hematology analyzer.

*e*-CHECK(XE) Ingredients (formulation)

*e*-CHECK(XE) consists of human red and white blood cells with a platelet component suspended in fluid medium. Each vial contains 4.5 mL of control material.

*e*-CHECK(XE) Storage

Store vials at 2-8o C.

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

*e*-CHECK(XE) Stability

1. Unopened and properly stored, *e*-CHECK(XE) is stable until the expiration date stated on the vial.
2. Open vial stability is 7 days when promptly refrigerated after each use.
3. Record the date on each vial upon opening.
4. Heat or freezing can damage *e-*CHECK(XE) 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.
5. If deterioration is suspected, call the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX).

**WARNING: POTENTIALLY INFECTIOUS MATERIAL.**

The human blood used in *e*-CHECK(XE) is non-reactive for Hepatitis B Surface Antigen and negative for antibodies to HIV-1, HIV-2, and Hepatitis C Virus using FDA specified techniques. However, no current tests can assure the absence of these pathogens. *e*-CHECK(XE) should be considered potentially infectious and must be handled with precautions used for human blood as described in CDC recommendations and in compliance with the Federal OSHA Bloodborne Pathogen Standard, 29 CFR, 1910.1030.

1. *e*-CHECK(XE) Commercial Controls Instructions for use
2. Remove *e*-CHECK(XE) vials from refrigerator and allow them to come to room temperature (18-25oC), for approximately 15 minutes.
3. Mix vials by gentle end-to-end inversion until the cell button in the bottom of the vial is completely suspended.
4. Frequency of Control use and review

*e*-CHECK(XE) control levels: \_**1&2**\_\_ will be run on 1st shift in the **primary** ode.

*e*-CHECK(XE) control levels:  **1&3\_** will be run on 2nd shift in the\_**primary**\_mode.

*e*-CHECK(XE) control levels: \_**2&3**\_\_ will be run on 3rd shift in the **primary** mode.

The charge tech reviews commercial controls every **\_week\_\_.**

1. Entering lot information for a new lot of Controls
2. Click on “**QC**” icon.
3. Click on Control tab.
4. Click on **[▼]** beside **Level**, and select level 1-3.
5. Click on **[▼]** beside **Mode**, and select “Manual” or “Closed” mode for the control level.
6. Click on **[▼]** beside **Lot** and select “New”.
7. If no data exist in the New lot file, click on **[LOT NO.]**.
8. Enter the lot number, and expiration date into the fields.
9. Click **[OK]** to update the NEW lot information.
10. Repeat steps 3-5 to enter lot information for the other levels of control.
11. If data exists in the NEW lot file, perform the “Change Lot” command.
12. “Change Lot” will move the NEW lot data to the CURRENT lot file, replacing any data that was present in the CURRENT lot file.
13. Before executing the “Change Lot” command, print data from the CURRENT file and/or save to a CD or USB memory device (refer to G. Recording and Storage of QC Data). Also save data for *Insight* (refer to J. *Insight* Quality Assurance Program – QAP).
14. QC Analysis

For peer group comparison purposes (QAP), run the control in the mode(s) most used for patient analysis – Closed (sampler) Mode or Manual Mode.

1. QC analysis in the **Closed** (Sampler) Mode with barcodes.
2. Place the room temperature, mixed control vials in the rack with the barcode labels facing the instrument.
3. On the Main Unit, press **[SAMPLER]**, and then **[START]** from the Select menu.
4. After the controls are analyzed, click on the “**QC**” icon on the IPU.
5. Click on the Control tab to display the L-J charts.
6. Click on **[▼]** beside **Level**, and select level 1-3.
7. Click on **[▼]** beside **Mode**, and select “Closed”.
8. Click on **[▼]** beside **Lot** and select “New” or “Current”.
9. Use the scroll bar on the right of the charts to view all the parameter charts.
10. Verify that all parameters fall within your established limits or within the package insert assay range during the parallel testing phase. If controls fall outside the range call the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8SYSMEX) to investigate possible control product failure.
11. QC analysis in the **Manual** Mode.
12. Press **[QC]** on the Main Unit. If “**QC”** is not displayed in the function menu, press **[MORE]** to see more menu options.
13. Press **[EXEC. QC]**.
14. Select the file from the list using **[▲]** or **[▼]**.
15. Press **[SELECT]**.
16. Aspirate the room temperature, mixed control vial via the whole blood aspiration pipette.
17. Once results appear on the Main Unit screen, compare them to the package insert assay range, using **[▲]** or **[▼]** to review all results.
18. On the Main Unit, press **[OK]** to accept the results. Press **[CANCEL]** to reject.
19. Follow steps c-g to analyze other levels of controls.
20. Verify that all parameters fall within your established limits or within the package insert assay range during the parallel testing phase. If controls fall outside of the range contact the Sysmex Technical Assistance Center at 1-888-879-7639 (1-888-8Sysmex) to investigate possible control product failure.
21. Auto-set Targets

Parallel test new controls by analyzing all three levels of control for a minimum of three times per day for 10 days prior to expiration of the previous lot. After a minimum of 30 data points are accumulated, auto-set the targets.

1. Click on **“QC”** icon.
2. Click on **“Control”** tab.
3. Click on **[▼]** beside Level, and select level 1-3.
4. Click on **[▼]** beside Mode, and select “Manual” or “Closed”.
5. Click on **[CHANGE LOT]** to move the NEW lot data to the CURRENT lot file replacing any data that was present in the CURRENT lot file. Print or back up any CURRENT data **BEFORE** executing the “Change Lot” command. Skip this step if the data is already in the CURRENT file.
6. Set the range of QC values to be used for auto-setting. Click on the green line (cursor) and drag to the left, or press **[CTRL]** and **[A]** to include all points.
7. Click on **[TARGET/LIMIT]**.
8. Click on individual parameters, or click and drag to select several parameters to be auto-set.
9. Click on **[AUTO SETTING]**.
10. Click **[TARGET]** check box to select (Do not select **[LIMITS]**). The targets will be auto-set to the mean of the points in the QC file.
11. Click **[OK]**.
12. Repeat steps 3-11 for each level of control.
13. Corrective Action for out of range QC Results

QC that is out of range must be repeated. If the repeat fails, run using fresh control material. If the fresh QC fails to recover acceptable values, consult the charge tech for instructions.

1. Recording and Storage of QC Data
2. Printing QC Data
3. Click on “**QC**” icon.
4. Click on “**Control**” tab.
5. Click on **[▼]** beside **Level**, and select level 1-3.
6. Click on **[▼]** beside **Mode**, and select “Manual” or “Closed”.
7. Click on **[▼]** beside **Lot** and select “New” or “Current”.
8. Set the range of QC values to be printed. Click on the green line (cursor) and drag to the left, or press **[CTRL]** and **[A]** to include all points.
9. Click **[REPORT]** on the menu bar.
10. Click on either “**Report (GP)**” for a graphic printout of the L-J Chart of data, statistics, targets and limits ***OR*** click on “**Ledger (LP)”** for line print of data, statistics, targets and limits.
11. Repeat steps c-h to print each level and mode of QC data.
12. Saving QC Data on removable media
13. Click on “**QC**” icon.
14. Click on “**Control**” tab.
15. Click on **[▼]** beside **Level**, and select level 1-3.
16. Click on **[▼]** beside **Mode**, and select “Manual” or “Closed”.
17. Click on **[▼]** beside **Lot** and select “New” or “Current”.
18. Set the range of QC values to be saved. Click on the green line (cursor) and drag to the left, or press **[CTRL]** and **[A]** to include all points.
19. Insert a USB memory device.
20. Click **[Save]**.
21. The “Save” dialog box displays. Enter a file name for the QC file. All file information and data will be saved under this file name.
22. From the drop-down box, select the appropriate drive for the storage device being used.
23. Click **[SAVE]**. Click **[CANCEL]**, if you do not wish to save the file.
24. Repeat steps c-k to save each level and mode of QC data.
25. Establishing Historical Limit %’s for Commercial Controls

For each parameter of each level of control, an acceptable range around the mean must be established. This range, called the *LIMIT %* is based on historical performance of the commercial control material when the instrument is in good working condition.

Historical LIMIT %’s are established using three different lots of *e*-CHECK(XE) (over a 6 month period for the 84 day-dated lot). Interim Limit %s, suggested by Sysmex, are used prior to establishing the analyzer-specific limits during the evaluation period. Once three lots of QC data are collected, add the cumulative CV values for each parameter to obtain a 3 CV% limit. These historical limits are manually entered for the LIMIT % in each file, for each level of control and are used for all subsequent lots of controls. These limits should provide acceptable error detection with a low probability of false rejection, and need not be reestablished.

1. Entering QC Limit %
2. Click on **“QC”** icon. Using the mouse and the computer keypad, manually enter the LIMIT % into the New files for all levels of control.
3. Click on **Control** tab.
4. Click on **[▼]** beside **Level**, and select level 1-3 for the limits you wish to enter.
5. Click on **[▼]** beside **Mode**, and select “Manual” or “Closed”.
6. Click on **[▼]** beside **Lot**, and select “New”.
7. Click on **[TARGET/LIMIT]**.
8. Click on the parameter you wish to set. The selected parameter appears in the upper right dialog box.
9. Click and drag over the value in the **LIMIT %** field to highlight it.
10. Enter the historical LIMIT % with the numeric keys, and press **[ENTER]**. The value is entered and the cursor moves to the TARGET field for the next parameter. Press **[ENTER]** again to highlight the next LIMIT for entry.
11. When all entries are complete, click **[OK]**.
12. *Insight* Quality Assurance Program (QAP)

The *Insight* account number is: **7333.**

The XE-5000 serial numbers are: **A1541**, and **A1545.**

Dayshift charge tech is responsible for saving the data to a USB memory device and submitting by due date. Data must be submitted no later than 3 days after the due date on the Sysmex *e*-CHECK(XE) assay sheet.

1. For peer group comparison purposes (QAP), run the control in the mode(s) most used for patient analysis – Manual or Closed (sampler).
2. Each lot has 2 data submission dates, approximately every 30 days for the 84-day dated product.
3. Review data and if desired, edit (delete) control data prior to submission. Ensure all QC data is plotted and no analysis error data is included (----) or (+++).
4. Insert Flash Drive into USB port on right side of IPU.
5. From the Menu Screen, click on the “Sysmex Insight” icon.
6. Click on **[▼]** beside **Material**, and select “Control”.
7. Click on **[▼]** beside **Level**, and select level 1-3.
8. Click on **[▼]** beside **Ana. Mode** and select “Manual” or “Closed”.
9. Click on **[▼]** beside **Lot**, and select “Current” or “New”.
10. Click on **[SAVE]**. Check that the name of the Flash drive appears in the **Save As** box. If not, click the drop down arrow and select the Flash drive from the list. The QC data selected will be saved with the file name: [Lot#.ins]
11. Perform steps (b-f) to save additional control files to the drive.

**NOTE** *Save each file separately. If saving both Closed and Manual Mode QC on the same device, or multiple instruments on the same device, separate folders on the drive should be created to save the data.*

1. Submit the data by uploading to the Sysmex *Insight* program on the Sysmex Web Site: [www.sysmex.com](http://www.sysmex.com). Contact the Sysmex Data Center for questions regarding data submission by telephone or e-mail.

Sysmex *Insight* phone: 847-996-4563

Sysmex *Insight* email [Insight@sysmex.com](mailto:Insight@sysmex.com)

1. Patient Controls / Instrument Corelation

Three patient samples (low, mid high) are run monthly comparing

instrument to instrument and mode to mode for the parameters listed

below. If any of these parameters fail to be within the manufacturer’s

acceptable limits, “s needed” maintenance must be performed. If Patients

controls/ correlation are still not within acceptable limits after maintenance

is performed, service must be contacted.

Parameters *Acceptable Limits* Parameters *Acceptable Limits*

WBC +/- 5 % NEUT% +/- 5.0

RBC +/- 2.5 % LYMPH% +/- 4.0

HGB +/- 2.0 % MONO% +/- 3.0

HCT +/- 2.5 % EO% +/- 2.0

MCV +/- 2.5 % BASO% +/- 1.0

PLT +/- 7 % NRBC% +/- 2.0

RET% +/- 20 %

1. Patient Moving Averages-XbarM (Xm)
2. Establishing XbarM (Xm) Historical Limit %

XbarM (XM) historical limits were determined by the following protocol as recommended by SYSMEX: ***The Sysmex Data Center suggests using 200 data points, representing 4000 samples in 20 patient size batches. Historical Xm limits are collected over multiple reagent lots and over at least one month, including all types of patient samples normally encountered.***

1. Batch size and Review Frequency

Our batch size for Xm is \_\_20\_\_ patient samples per batch. Each point on the Xm QC graph represents one batch.

Technologist will check Xm charts on every shift.

The presence of an “X” is indication that a batch is out.

If one batch is out, the technologist will monitor the Xm charts throughout the shift.

If two consecutive batches are out, the technologist will rerun two levels of control and continue to monitor throughout the shift.

If three consecutive batches are out, the technologist will take the analyzer out of service, perform patient recovery and call the hotline.

Supervisor will review Xm charts every week.

Switching Xm OFF and ON

1. Click on “**QC**”icon on IPU. Click on “Setting” at bottom of screen.
2. Select the X-bar M tab. Click “Control”, then **[OK]** to save and exit.
3. Press **[QC]** from the function menu of the Main Unit. Press **[MORE]** if the QC function is not displayed.
4. Press **[XM STT/STP]**. The Xm symbol in the upper right of the LCD Main Unit screen will be present when Xm is on, and disappear when it is switched off.

# CALIBRATION

## SCS-1000 Calibrator

**SCS-1000** is a secondary whole blood calibrator for use with the Sysmex XE-5000 hematology analyzer. Assay values for primary parameters are traceable to reference methods.

SCS-1000 Ingredients (formulation)

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.

SCS-1000 Storage

Store vials in the upright position, at 2-8°C. **Do not** freeze or expose to excessive heat.

SCS-1000 Stability

1. Unopened and properly stored, SCS-1000 is stable until the expiration date stated on the vial.
2. Open vial stability is 4 hours.
3. Storage outside of 2-8°C can damage 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).
4. Use of the product at environmental temperatures that exceed 86oF (30°C) can reduce calibration accuracy.

Initial calibration is performed during installation and verified bi-annually during preventive maintenance (PM) 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 service representative upon installation.

The laboratory must verify calibration every six months or on an "as-needed" basis to ensure accuracy of system. Calibration verification 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 be performed by review and documentation of commercial control and Xm QC data, proficiency testing results and patient control testing results. The operator may calibrate the following parameters using SCS-1000 calibrator: WBC, RBC, HGB, HCT, PLT and PLT-O. **Before calibration, ensure that the XE-5000 is both clean and precise.**

1. **Precision Check**
2. Perform routine 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 XE-5000 runs 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 etc.
6. have morphologically and numerically normal CBC.
7. be drawn in potassium EDTA anticoagulant tube using proper collection technique.
8. have a minimum of 2 mL of sample.
9. On the Main Unit, select **[CAL]** from the function menu. Press **[MORE]** if CAL is not displayed in the function menu.
10. Select **[Precision]** from the CAL sub-menu. The screen displays WBC, RBC, HGB, HCT and PLT precision limits (CV%) for each parameter. Use **[◄]** or **[►]** to view PLT-O.
11. On the IPU, click the “Controller” icon and then double-click “Precision Check”.
12. Analyze the sample 11 times in the Manual Mode. After each analysis, the results display and the cursor moves to the next line. The mean, SD, and CV% are calculated on the last 10 analyses.
13. After 11 analyses, the CV% values for the six parameters display with the judgment of G=Good, NG=No Good.
14. ‘No Good’ indicates the CV% is higher than the acceptable limits, “Precision Check has failed. Take corrective action” displays.
15. If all results are ‘Good’, press “Record”on the Precision Check screen and the Precision Check dialogue box displays “Precision Check has passed. Go to Calibration step. Record Precision Check data?” Press **[OK]**.
16. **Calibration Check (optional)**
17. Prepare the Sysmex SCS-1000 calibrator according to the product insert.
18. On the Main Unit, select **[CAL]** from the function menu. Press **[MORE]** if CAL function is not displayed.
19. Select “Calibrator”from the CAL sub-menu.
20. Use the numeric keys, followed by **[ENTER]** to enter the target values for each parameter from the SCS-1000 assay sheet.
21. On the IPU click the “Controller”icon and then double-click the “Calibrator Calibration”icon.
22. Analyze the SCS-1000 calibrator in the manual mode six times.
23. After six analyses, the last five analyses are used to calculate the Range Values and Delta percents. The parameter calculated values will be highlighted if they are out of range.
24. Press **[EXECUTE]** from the function menu. The Select Calibration Item Dialogue box displays.
25. In the following cases, **[EXECUTE]** will not become effective. Take corrective action by referring to “Chapter 10: Troubleshooting”, and analyze a fresh vial of calibrator. If problems persist contact the Technical Assistance Center.

* New Compensation Rate is <80
* New Compensation Rate is >120
* [Current Compensation Rate – New Compensation Rate] is > 5
* Range Value > Max Range
* Delta Percent > Service Limit Screen

1. If the Range Values and Delta Percents are within acceptable limits, the check box for the parameters which need calibration will be checked automatically. Press **[OK]** in the Select Items for Calibration Screen and the Execute Calibration message dialogue is displayed.
2. Press **[OK]** to send the new calibration information values to the Main Unit, or **[CANCEL]** to reject the change and exit the program.
3. Using another fresh vial of calibrator, verify the calibration by repeating the Calibration Check procedure. If you have “Accept Limit” messages displayed in the Interpretive Message column on all selected parameters, the system is calibrated properly. Do not execute calibration, exit the Calibration function.
4. Print the Calibration History.
5. Click on the “Menu” icon.
6. Click on the “Controller” icon.
7. Click on the “Calibration History” icon.
8. Click on the calibration date in the Calibration History list.
9. Click on “Report” and select “Ledger (LP)” or print the screen by clicking “File”, “Print” from the menu bar.
10. Following calibration, analyze commercial controls.

# V. SUPPLIES & REAGENTS

1. Supplies
2. De-ionized water
3. Plastic squeeze bottles
4. Clorox™ bleach (use when CELLCLEAN is indicated)
5. Sysmex reagents
6. Tri-level commercial controls, *e*-CHECK(XE)
7. Sysmex Reagents
8. Eleven Sysmex reagents and bleach are used on the Sysmex XE-5000.
9. All reagents are used at room temperature and are to be used within the manufacturer's expiration date on each container.
10. Record date received and date opened on container.

**All reagents are azide free and they are intended for *in vitro* diagnostic use**

**only. Do not ingest. Avoid skin and eye contact. Flush with plenty of water**

**immediately. Consult with a physician in case of ingestion and/or eye**

**contact.**

|  |  |  |
| --- | --- | --- |
| **REAGENT** | **ABBREVIATION** | **OPEN EXPIRATION** |
| CELLPACK | **EPK** | 60 days |
| CELLSHEATH | **ESE** | 60 days |
| STROMATOLYSER-4DL | **FFD** | 60 days |
| STROMATOLYSER-4DS | **FFS** | 60 days |
| STROMATOLYSER-FB | **FBA** | 60 days |
| STROMATOLYSER-IM | **SIM** | 60 days |
| RET-SEARCH (II) diluent & dye | **RED** | 60 days |
| STROMATOLYSER-NR(L) STROMATOLYSER-NR(S) | **SNR** | 60 days |
| SULFOLYSER | **SLS** | 90 days |

## NOTE: See Sysmex XE-5000 Instructions for Use, Chapter 4, for reagent intended use, storage, and stability.

## CLOROX™ Clorox-brand bleach is recommended for use in cleaning and shutdown of the XE-5000 analyzer whenever CELLCLEAN is indicated.

Clorox Ingredients

Sodium Hypochlorite 6.00% (approximately)

Clorox Health Risk

**WARNING**: Clorox: Avoid acidification or contact with ammonia containing products which can generate hazardous chlorine gas. Clorox contains a strong oxidizing agent that could cause substantial but temporary eye injury, may irritate skin and 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.

1. **REAGENT REPLACEMENT**
2. When the XE-5000 runs out of a reagent, the alarm sounds and the LCD displays a “Replace Container” message with the abbreviation for the reagent to be replaced.

**Note:** *STROMATOLYSER- NR and RET-SEARCH (II) consist of a diluent/lyse and pouch of dye, and* ***must be replaced as a set****.*

1. Press **[HELP]** for instructions and to silence the alarm.
2. Press **[OK]** from the function menu. A list of reagents with “Replace” beside the empty reagent(s) appears.
3. Using the handheld barcode reader, scan the lower barcode (EAN-128) on the reagent container. Use the barcode on the box for RED, SNR, and FFS. Reagent lot information displays on the reagent screen.
4. If necessary, reagent information may be entered manually. Press **[MANUAL]** from the function menu. Using the alpha/numeric keypad, enter the lot number, expiration date, open expiration days, and volume of reagent container. Press **[OK]**.
5. Verify that the label on the line removed on the empty reagent matches the new reagent container.
6. Using care not to contaminate the reagent line, open the new reagent container, remove the line from the empty container and drop it directly into the new container.

**Note:** *When STROMATOLYSER-4DS is replaced, be sure to position the FFS label on the reagent line the same direction as the label on the dye pouch. (See label on IMI detector door.)*

**Note:** *Special care must be taken when replacing the STROMATOLYSER-IM reagent.*

* *Place the float switch support plate underneath the spout kit on the new reagent container.*
* *Ensure that the O-ring is located in the groove of the spout. Remove any dust with a clean alcohol pad.*
* *Remove the Quick Connector from the empty container by pulling up on the locking collar.*
* *Before reconnection, clean the inner part of the Connector with an isopropyl alcohol pad.*
* *Place the Quick Connector onto the SIM spout kit by pulling up on the locking collar, applying pressure to the connector, and releasing the locking collar to lock into position. Twist slightly to ensure a tight fit.*

1. After tightening the spout cap on the new container, press **[EXECUTE]** from the Function menu on the Main Unit. The reagent will be aspirated to satisfy the sensor, and the reagent replaced will appear on the Reagent Log in Controller menu.

## VI. MAINTENANCE

To ensure that the instrument can function in its best state, it is necessary to perform scheduled maintenance. This section includes written procedures for performing periodic maintenance. Refer to **Sysmex XE-5000 Instructions for Use**, for detailed illustrated procedures.

**IMPORTANT NOTE FOR ALL MAINTENANCE**

*Clorox Bleach is a 6% sodium hypochlorite solution. The Sysmex Instructions for Use recommends using a 5% sodium hypochlorite solution. To make a liter of 5% solution from Clorox, use the formula below. Store stock 5% bleach in a dark place for up to one week to prevent solution degradation from exposure to light.*

**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.

1. **Clean SRV after 30,000 cycles or when “Clean SRV” message displays**

**(XE-5000 Instructions for Use)**

1. Switch Pneumatic Unit off. Wait for pressure to drop to zero.
2. Open top cover of XE-5000. Set stop bar to prevent cover from falling.
3. Place paper towels beneath SRV area to catch any reagent drips.
4. Remove tray from beneath SRV.
5. Push down on manual rinse cup to remove it from manual aspiration pipette.
6. Remove constant pressure screw on SRV.
7. Remove the sample rotor valve assembly. Center rotary portion is removed by gently twisting and sliding sections apart.
8. Clean surfaces of SRV with 1:10 filtered bleach.
9. Rinse with DI water and reassemble wet. Valve surfaces should be free of dirt and dust.
10. When reassembling SRV, place center rotary portion with notch facing upward and metal knob between two stoppers.
11. Reinstall constant pressure screw that holds SRV on finger-tight.
12. Gently push manual rinse cup up with both hands. If manual rinse cup is not re-installed properly, then a “Rinse Motor Error” may occur.
13. Clean and replace SRV Tray.
14. Turn Pneumatic Unit power on.
15. Perform an Autorinse to check background counts.
16. Verify proper instrument performance by analyzing QC.
17. To reset SRV counter:
18. Press “TEST” then “Status” on the Main Unit function menu.
19. Select “Counter”.
20. Use **[▲]** or **[▼]** to select item [toggles SRV & PIAS only].
21. Press **[OK]** on function menu to reset to zero.
22. Record on Maintenance Log.
23. **Replace Piercer or when “Change Piercer” message is displayed**

## (XE-5000 Instructions for Use)

1. Turn OFF Main Unit Power and open front cover of XE-5000.
2. Loosen the fixing screws and remove the CP Cover.
3. Remove the fixing screws of the cap piercer cover and remove the cover.
4. Remove the tubes and rubber joint which are connected to the cap rinse cup and piercer.
5. Install the fixing board to the piercer using three screws.
6. Loosen the fixture lock screw; remove three screws which fix the rinse cup.
7. Remove the piercer and dispose of it.
8. Set a new piercer to the slider and piercer support and tighten the fixture lock screw.
9. Loosen slightly the screw A on the piercer fixing board. Slide the rinse cup and place it against the slider surface, then fix the rinse cup with three fixing screws.
10. Remove three screws from the fixing board and remove the board.
11. Install the tubes and rubber joint which are connected to the rinse cup and piercer.
12. Install the piercer cover and CP cover.
13. Close the front cover.
14. Restart system per Section VI. Verify proper instrument performance by processing quality control.
15. To reset the piercer cycle counter
16. Press “TEST” then “Status” on the Main Unit function menu.
17. Select “Counter”.
18. Use **[▲]** or **[▼]** to select item [toggles SRV & PIAS only].
19. Press **[OK]** on function menu to reset to zero.
20. Record on Maintenance Log.
21. **XE-5000 As-needed Maintenance**
    * + 1. **Clean manual rinse cup**

**(XE-5000 Instructions for Use)**

* Perform if blood adheres to manual rinse cup or if clogs are found.
* Convenient to perform as part of SRV cleaning.

1. Switch Pneumatic Unit off. Wait for pressure to drop to 0.
2. Open top cover of XE-5000. Set stop bar to prevent cover from falling.
3. Using both hands, push rinse cup down to remove it from aspiration pipette.
4. Remove small tube #2 tube from rinse cup. **Do not** remove other tube.
5. Rinse manual rinse cup center opening and side port with water and wipe dry.
6. Reinstall tube #2 on manual rinse cup.
7. Insert aspiration pipette into center of manual rinse cup. Using both hands, push manual rinse cup up until it stops. Make sure tubes pass behind manual rinse cup.
8. Turn Pneumatic Unit power on. Press **“Start”** switch and observe for proper alignment of manual rinse cup and 2 tubes. If manual rinse cup is not re-installed properly, a “Rinse Motor Error” may occur.
9. Press **[AUTORINSE]** on the Main Unit to check background counts.
10. Record on Maintenance Log.
    * + 1. **Perform Rinse Flow Cell Cleaning**

**(XE-5000 Instructions for Use)**

* Perform either when “Execute Rinse Flow Cell” **(every 400 Retic Counts)** message displays

1. Message **“Execute Rinse Flow Cell”** displays. Press **[HELP]** to display prompts. Press **[OK]** to select this cleaning mode.
2. Hold 1mL tube of 5% filtered sodium hypochlorite (Clorox bleach) under manual aspiration pipette.
3. Press **[START]** and Rinse Flow cell will be executed.
4. Record on Maintenance Log.

* Performif Flow Cell in optical detector is suspected to be dirty.

1. Select “Maint” on function menu of Main Unit LCD panel keypad. If needed, press **[MORE]** to change function menu.
2. Hold 1mL tube of 5% filtered sodium hypochlorite (Clorox bleach) under aspiration pipette.
3. Press **[4]** to begin “Rinse Flow cell”.
4. Record on Maintenance Log.
   * + 1. **Cleaning the Sample Rotor Valve Tray**

* Perform if sample rotor valve tray displays blood product remnants.

1. Switch Pneumatic Unit OFF and wait for pressure to equal zero.
2. Open the Main Unit front cover.
3. Remove the Sample Rotor Valve Tray.
4. Clean the Sample Rotor Valve Tray using running water.
5. Make sure that no residue remains in the Sample Rotor Valve Tray and wipe off moisture.
6. Install the sample rotor valve tray to its original position.
7. Close the Main Unit front cover and switch on the Pneumatic Unit.Record on Maintenance Log.
   * + 1. **Cleaning the Piercer Tray**
   * Perform if the piercer tray displays blood product remnants.
8. Switch Pneumatic Unit OFF and wait for pressure to equal zero.
9. Open the Main Unit front cover.
10. Loosen the CP cover.
11. Remove the Piercer Tray.
12. Clean the Piercer Tray using running water.
13. Make sure that no residue remains on the Piercer Tray and wipe off moisture.
14. Install the Piercer Tray to its original position.
15. Install the CP cover and close the Main Unit front cover.
16. Switch on the Pneumatic Unit.
17. Record on Maintenance Log.
    * + 1. **Perform Air Bubble Removal for Flow Cell**

(XE-5000 Instructions for Use)

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

1. Select “Maint” on function menu of Main Unit. If needed, press **[MORE]** to change function menu.
2. Press **[2]** to begin Air Bubble removal.
3. Record on Maintenance Log.
   * + 1. **Remove RBC or IMI Clogs with Clog Removal Sequence**

(XE-5000 Instructions for Use)

* Perform when “RBC Clog Error”, “RBC Bubble Error”, or RBC/PLT Sampling Error” message displays.
* Perform when “IMI Count Too Long” or “IMI Slow To Start” message displays.

1. When error message is displayed, press **[HELP]** to display prompts.
2. Press **[OK]** to begin Clog Removal Sequence.

Alternate Method for Performing Clog Removal

(when no error is displayed)

1. Select “Maint” on function menu of Main Unit.
2. If needed, press **[MORE]** to change function menu.
3. Press **[3]** to begin “Clog Removal”.
4. Record on Maintenance Log.

## CALCULATIONS

A. If a vote out appears on the sample data for NRBC’s a smear review should

be performed. If NRBC’s are present a correction for the WBC count will be

required. Also in the event that 5 or more megakaryocytes were counted on

a manual differential, a correction for the WBC will also be required substituting the number of NRBCs with the number of megakaryocytes. Use the following calculation when correcting the WBC.

\_\_\_\_Uncorrected WBC count x 100\_\_\_\_\_ = corrected WBC count (mm³)

Number of NRBC’s per 100 WBC’s + 100

1. The ANC (absolute neutrophil count) is automatically calculated on specimens ordered as a CBCD. If the neutrophil result is voted out on the auto diff, the instrument cannot calculate the ANC. When the auto diff is voted out and a request has been made for the ANC result, the tech will be required to do a manual diff. The neutrophil result from the manual diff can then be used to calculate the ANC using the following calculation:

(Segs + Bands) x WBC= ANC

When only a CBC is ordered, there will be no ANC. If the physician calls

requesting an ANC, it can be calculated as above by doing a manual diff to

obtain the neutrophil result or the specimen can be rerun in the manual

mode and the ANC result can be retrieved from the browser. The ANC on

browser will be the Neut# . To report it in Meditech, you must move the

decimal point three places as Meditech reports it as #/ul. E.g. the Sysmex

browser has Neut# as 9.43. The ANC result would be entered as 9430/ul. It

can be entered as a comment under the WBC result.

C. Retic add-ons for microtainer specimens which already had a CBC or CBCD

run can be entered manually into Meditech without the need to rerun the

specimen or request a redraw if the specimen is now QNS. Search the

specimen on the Sysmex explorer and obtain the retic panel results. The

Retic # must have the decimal point moved three places. E.g.

Retic panel on Sysmex explorer: Ret % 8.33

Ret # 0.2216

IRF 0.086

Results to Meditech: Ret % 8.33

**Ret # 221.6**

IRF 0.086

## REPORTING RESULTS

1. ***ADULT REFERENCE RANGE***

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter | Reference Range | Parameter | Reference Range |
| WBC: | 4.0-11.0 | Neut % | 50-70 |
| RBC | male: 4.60-5.90 | Lymph % | 20-40 |
| female: 4.00-5.10 | Mono % | 0-12 |
| HGB | male: 12.0-15.0 | Eo % | 0-5 |
| female: 12.0-15.0 | Baso % | 0-2 |
| HCT | male: 40.0-49.0 | IG % |  |
| female: 39.0-43.0 | NRBC % |  |
| MCV | male: 81.0-99.0 | Neut # | 1.9-8.0 |
| female: 81.0-99.0 | Lymph # |  |
| MCH: | 27.0-33.0 | Mono # |  |
| MCHC: | 32.0-37.0 | Eo # | 50-500 |
| RDW-CV: | 11.5-14.5 | IG# |  |
| PLT: | 125-490 |  |  |
|  |  | RET % | 0.5-2.5 |
| IPF |  | RET # | 12.96-107.03 |
|  |  | IRF | 0.004-0.252 |

***B. PEDIATRIC REFERENCE RANGE***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Parameter | Reference Range | | Parameter | Reference Range | | |
| OD | 3M | OD | 15D | 11Y |
| WBC: | 4.5 -15.0 |  | Neut % | 25-70 |  | 50 – 70 |
| RBC | 4.00-5.90 | 4.00-5.10 | Lymph % | 20 - 70 |  | 20 – 40 |
| HGB | 11.0-20.0 | 11.0-14.5 | Mono % | 0 - 7 |  | 0 - 12 |
| HCT | 34.0-60.0 | 34.0-40.0 | Eo % | 0-5 |  | 0-5 |
| MCV | 81.0-99.0 |  | Baso % | 0-2 |  | 0-2 |
| MCH: | 27.0-33.0 |  |  |  |  |  |
| MCHC: | 32.0-37.0 |  |  |  |  |  |
|  |  |  | Neut # | 1.1-10.5 |  |  |
| RDW-CV | 11.5-14.5 |  |  |  |  |  |
|  |  |  |  |  |  |  |
| PLT: | 125-490 |  | RET % | 2.5 – 6.0.5- | 0.5 – 2.5 |  |
|  |  |  | RET # | 152.3 - 275.5 | 12.9 -107.0 |  |
|  |  |  | IRF | 0.233 - 0.382 | 0.004-0.252 |  |

1. ACCEPTABLE REPORTING FORMAT

All results are sent to the Meditech computer system for review and verification by the technologist. See limitations of procedure for acceptable linearity ranges and known interfering substances. Dilutions are usually adequate for those values that fall outside the analyzer linearity. Values out because suspicions of an interfering substance please refer to Recognizing and Handling Unusual CBC Results. This document contains detailed instructions on proper treatment of sample to correct effected result or results.

1. REPORTING ABNORMAL RESULTS TO PHYSICIANS

All Alert values are entered in the Meditech computer system and flagged when transmission from the analyzer occurs. The technologist must review results and electronically document that he or she notified the nurse and or the doctor whose care the patient is under.

## PROCEDURE NOTES

1. If there are marked changes in plasma constituents, (i.e. very high glucose), perform a plasma replacement and rerun specimen.
2. Analysis of the specimen on XE-5000 is recommended before removing the cap to make a smear.
3. **Do not** place samples on a mechanical rocker. Excessive mixing may induce platelet clumping and alter white cell membranes resulting in false interpretive messages.
4. Clorox, a filtered bleach, is recommended for use in cleaning.,Clorox must be diluted to a 5% Sodium Hypochlorite concentration before preparing further dilutions recommended for maintenance.
5. For troubleshooting specifics refer to the Sysmex XE-5000 Main Unit Instructions for Use.

## LIMITATIONS OF PROCEDURE

1. **XE-5000 MANUFACTURER STATED LINEARITY**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Range** | **Units** |
| WBC | 0-440.0 | x103/μL |
| RBC | 0-8.00 | x106/μL |
| HGB | 0-25.0 | g/dL |
| HCT | 0-75.0 | % |
| PLT | 0-5000 | x103/μL |
| RET# | 0-72 | 104/μL |
| RET% | 0-23 | % |
| NRBC# | 0-19.2 | x103/μL |
| NRBC% | 0-464 | /100 WBC |
| HPC# | 0-500 | cells/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 1:5 and use the capillary mode.
2. Note the use of dilution for linearity on the patient report.
3. **POSSIBLE SAMPLE INTERFERENCES**
4. Specimens must be free of clots and fibrin strands.
5. 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.
6. Red cell fragments, microcytic RBC's or white cell cytoplasmic fragments may interfere with automated platelet counts. An optical platelet may be performed to avoid this interference.
7. 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.
8. Extremely elevated WBC's may cause turbidity and increase the hemoglobin, in addition to RBC and HCT values.
9. Severely hemolyzed samples (in vitro) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
10. Giant platelets and clumped platelets may falsely elevate the WBC count and falsely decrease the platelet count.
11. 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 analyze and multiply by 1.11 dilution factor.
12. Abnormal paraproteins found in Multiple Myeloma patients can falsely increase the HGB. To correct HGB perform plasma replacement.
13. Abnormal proteins as seen in Multiple Myeloma and Waldenstrom's macroglobulinemia may falsely increase the WBC count.
14. Lipemia falsely elevates the HGB & MCHC. Perform a plasma replacement or plasma blank procedure.
15. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK.
16. Abnormal proteins, such as found in multiple myeloma, may cause interference and falsely elevate HGB and MCHC results.
17. Rocking specimen excessively, may affect the WBC differential.
18. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.

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