Automated Hematology Analyzer

Sysmex XW™-100

Instructions for Use Manual

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XW-100 Automated Hematology Analyzer

Intended Use

The XW-100 Automated Hematology Analyzer (XW-100) is a quantitative automated hematology analyzer intended for *in vitro* diagnostic use to classify and enumerate the following parameters for venous whole blood anti-coagulated with K_2/K_3 EDTA: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#. It is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.

Intended Operators

Intended operators of the Sysmex XW-100 must have at a minimum an earned high school diploma or equivalent.

Note:
Operation of instruments and devices outside of recommended manufactures guidelines may result in inaccuracies.

US federal law restricts this device to sale by or on the order of a physician (or properly licensed medical practitioner).

Summary

The XW-100 is an electrical resistance type blood cell counter. This technology may be variously referred to as Direct Current, (DC) or impedance. The analyzer uses a human whole blood specimen and produces results for 12 hematology parameters including the basic CBC, three part WBC differential and MCV.

Cautions and Warnings

Electrical 

- NEVER insert the power plug into power sockets other than AC100-240 V. Please note that the analyzer must be grounded.
- Avoid damage to the power cord. Unplug by gripping the plug NOT by pulling the cord.
- If the analyzer emits unusual odors or smoke or if it leaks fluids, switch the analyzer off, unplug the power cord and contact the Sysmex Technical Assistance Center (TAC) immediately.
- Do not spill blood or other fluids on or inside the analyzer. Do not place metal objects such as staples or paper clips on the analyzer as these could cause a short circuit.
- In the event of a short circuit switch the analyzer off, unplug the power cord and contact the Sysmex Technical Assistance Center (TAC) immediately.

EMC Information

- This instrument complies with IEC 61326-1 (Class B, Group 1, Industrial environment)
- This equipment might be used in areas other than laboratories.
- EMI (Electromagnetic Interference): For this standard the requirements of class B are fulfilled.
- EMS (Electromagnetic Susceptibility): For this standard the minimum requirements with regards to susceptibility are fulfilled.
- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
- It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.
- If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- When XW-100 is installed, keep following distance between XW-100 and radio transmitter:

Radio transmitter	**Maximum power (W)**	**Minimum separation distance (m)**
Mobile phone Wireless LAN	0.2W～	0.9m～
Digital Convenience Radio	5W～	4.5m～

Biohazard 

- All parts and surfaces of the analyzer as well as QC vials and contents must be regarded as potentially infectious due to its contact with blood. To avoid infection:
    - Use protective lab coat, eye protection and disposable gloves when operating or maintaining the analyzer.
    - NEVER touch the analyzer, accessories or waste fluids with bare hands.
    - Should you inadvertently come in contact with potentially infectious materials or surfaces immediately rinse the affected skin area thoroughly with water and follow your facilities prescribed cleaning and decontamination procedures.
    - After completion of work with the analyzer wash your hands thoroughly with soap and water or a disinfectant hand cleanser.

XW pack D and XW pack L Reagents, XW CELLCLEAN™, and XW QC CHECK™

Description

XW pack D, (2 x 2L) is a proprietary reagent which is used to blank the system, dilute the whole blood sample prior to analysis and rinse the analyzed sample out of the system post analysis. This reagent is shipped fully reconstituted and ready for use.

XW pack L (2 x 250mL) is a proprietary reagent which is used to lyse RBCs during the testing process to determine WBC and Hemoglobin parameters. This reagent is shipped fully reconstituted and ready for use.

XW CELLCLEAN™ is a proprietary single use weekly care fluid which keeps the aspiration pipette, sample path, and rinse cup clean and operational.

- 20 single use tubes per box
- **Note: Weekly care must be performed every seven calendar days. The system will not process patient samples until weekly care is performed.**
- XW CELLCLEAN™ is shipped fully reconstituted and ready for use.

XW QC CHECK™, (2 vials of each level per package) is a proprietary 3 level control which is performed to verify correct system performance.

- XW QC CHECK™ is shipped fully reconstituted and ready for use.

Intended Use:

The XW QC CHECK is a stabilized whole blood matrix designed for statistical process control of the Sysmex XW-100 automated hematology analyzer. It is not intended for calibration of the analyzer. Assayed parameters include: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#, RDW-SD, RDW-CV and MPV.

- Other WBC%/# is comprised of eosinophils, basophils and monocytes.
- Two vials of each level are included. The first vial (primary) has sufficient fill quantity and should be used each testing day until a new lot arrives unless the primary vial is lost or broken.

- XW QC CHECK should be placed on standing order for delivery every 28 days when the analyzer is in use.
- **Note:** QC must be performed as follows:
    - Every 8 hours of instrument use
    - When a new lot of reagent is used
    - After completing weekly care (NOTE, a description of weekly care can be found in the Operators Quick Guide)
- The system will prompt users when QC is required and will not allow patient samples to be tested until QC is performed**.**

Handling

- Follow the on-screen XW QC CHECK vial mixing instructions correctly; DO NOT shake.
- All reagents, XW CELLCLEAN™ and QC materials are fully reconstituted and are ready for use upon arrival.
- Read and follow all labeling on reagents, XW CELLCLEAN™ and QC materials prior to use.
- Avoid direct contact with reagents, XW CELLCLEAN™ and QC materials.
- In case of eye contact with reagents, XW CELLCLEAN™ or QC rinse thoroughly with water and consult a physician immediately. Observe the recommendations in the downloadable Safety Data Sheet (SDS).
- SDS sheets for XW-100 reagents, XW CELLCLEAN™ and QC materials can be downloaded from the Sysmex Customer Resource Center website https://www.sysmex.com/us/en/Pages/default.aspx
- DO NOT store reagents or QC on top of the analyzer.
- Reagents in use should be placed next to the analyzer, not on top.
- If reagents spill near the power cord or other electronic appliances there is a risk of electrical shock. Switch the instrument off and unplug the power cord before cleaning up the spill and decontaminating the spill area.
- Be aware of and observe precautions and warning labels on the analyzer.

Storage / Stability

- All XW-100 reagents, XW CELLCLEAN™ and XW QC CHECK™ should be stored at room temperature (59° - 77° F or 15 – 25° C).
- Store XW CELLCLEAN™ in the light protective box it was shipped in until use.

- Keep extra reagent, XW CELLCLEAN™ and XW QC CHECK™ stored in a clean, dry location.
- The analyzer will not allow the use of reagents, XW CELLCLEAN™ or XW QC CHECK™ that are past their expiration date, open container stability limit or container cycle limit.

XW-100 Instrument

Use and Function

- Installation of the analyzer must be performed by following the *XW-100 Start-up Quick Guide* then proceeding to the on-screen directions.
- Operators must keep hair, fingers and clothing away from the sample door.
- Operators must NEVER remove the analyzer's outer housing.
- Operators must complete the XW-100 on-line registration prior to operating the analyzer.

Installation Procedures and Requirements

- The analyzer must be installed in a clean dry location close to power and away from direct sunlight, water or excessive draft. The space must be adequate in size for the analyzer itself and reagents which sit beside. The analyzer measures 7.3" (W) x 18.1" (D) x 13.8" (H) and weighs 38lbs.

- To install the system, follow first the steps from the *XW-100 Start-up Quick Guide*, then the on-screen installation instructions.

- The analyzer SHOULD NOT be operated at temperatures below 12°C (54°F) or above 33°C (91°F), a relative humidity below 30% or above 85% or atmospheric pressure below 1.02 PSI (roughly 10,000 feet above sea level) or above 1.5 PSI (below sea level).

Specifications and stability

- Day-to-Day; XW QC CHECK run for 18 days was determined to be:
  - WBC; ≤ 3.5%
  - RBC; ≤ 2.0%
  - Hemoglobin; ≤1.5%
  - Hematocrit; ≤ 2.0%
  - Platelet; ≤ 6.0%

Fluctuations of 10% voltage do not affect XW-100 results

Operating Instructions

Once weekly care and QC requirements have been satisfied, the analyzer will show the "ready for testing" screen. The instrument requests the operator to confirm a purple top collection tube was used. The operator should answer "Continue," and follow the on-screen prompts. Follow all instructions on the results printout.

Calibration Procedures

The XW-100 requires no on-site calibration. The system is shipped factory calibrated and ready for installation and operation. When the system requires calibration, due to the uncorrectable failure to pass QC, Sysmex will ship a replacement system. After the first-time start-up procedure, performance of weekly care and QC, the replacement system is ready to operate.

Limitations

- The XW-100 generated results should be used as an adjunct to other clinical findings. Should any results be inconsistent with other clinical findings or past CBC test results, the Clinician is advised to redraw and retest the patient or send the patient sample to a reference laboratory for furtheranalysis.
- Some patient samples will require a repeat in order to confirm results for parameter(s) that are outside normal limits. Should you elect not to repeat the initial test, the analyzer WILL NOT print any results. If the repeat test does not correlate with the first test results to a statistically acceptable degree, the result will not be printed. The Clinician is advised that further testing isrecommended.
- Some patient samples will generate flags caused by various interfering substances. When flags are present, one or more parameter results could be inaccurate or questionable. In such cases the potentially affected parameter results will not print. The Clinician must refer to the *XW-100 Clinician's Quick Guide* for more information as to the causes and recommended actions in such instances.
- Samples that are known or subsequently determined to be grossly lipemic or hemolyzed must not be tested on the analyzer as they will generate incomplete results (some

parameters results will not be printed). Such samples must be sent out to a reference laboratory.
- Collection tubes other than purple top EDTA tubes MUST NOT be used.
- Patients less than 2 years of age MUST NOT be tested on the analyzer because the performance characteristics for this age range have not been determined.

Specimen Collection and Preparation

- The XW-100 analyzer accepts standard 12-15 mm, 2 – 4mL draw purple top vacuum tubes. Both K_2 and K_3 EDTA are acceptable. Tubes other than purple top EDTA tubes MUST NOT be used.
- Blood should be collected following the tube manufacturer's instructions for minimum fill volume and well mixed post draw to distribute the anti-coagulant.
- Good phlebotomy and biohazard safety practices should be observed at all times.
- Operators must label the specimen correctly and/or only accept a properly labeled specimen from another staff member for testing on the XW-100.
- All parts and surfaces of the analyzer as well as QC vials and contents must be regarded as potentially infectious due to its contact with blood. To avoid infection:
    - Use protective lab coat, eye protection and disposable gloves when operating or maintaining the analyzer.
    - Disposable gloves should be removed after operating or maintaining the analyzer to perform other duties. When returning to operate or maintain the analyzer, a new pair of disposable gloves should be used.
    - NEVER touch the analyzer, accessories or waste fluids with bare hands.
    - Should you inadvertently come in contact with potentially infectious materials or surfaces immediately rinse the affected skin area thoroughly with water and follow your facilities prescribed cleaning and decontamination procedures.
    - After completion of work with the analyzer wash your hands thoroughly with soap and water or a disinfectant hand cleanser.
- Minimum blood fill volumes for use on the analyzer are 1mL for 12-15 mm vacuum tubes. Running tubes with lower than minimum fill volume will result in suppressed values for test parameters.
- Test samples containing various interfering substances or rare cells and samples from patients with various pathological conditions can initially generate compromised results. In these cases, the system prints result flags and does not print numerical results. Refer to the *XW-100 Clinician's Quick Guide* for additional information.

Specimen Storage

- It is recommended that samples be tested on the analyzer immediately following collection, however properly collected samples can be stored at either room temperature or refrigerated and run subsequently on the analyzer. Whole blood samples stored at

room temperature (59 - 77° F or 15 – 25°C) are stable for up to 8 hours and samples stored refrigerated (36 - 46° F or 2 - 8° C) are stable for up to 36 hours. Specimens that have been stored refrigerated should be warmed as instructed by the analyzer prior to running. Any specimen that has been stored should be mixed thoroughly as instructed by the analyzer prior to running.

Step-by-Step Procedure

1. Follow the *XW-100 Start-up Quick Guide* and on-screen instructions if you are installing and operating the system for the first time or the system has been powered down and moved or powered down for over 15 minutes, (as instructed by the system on-screen prompts).
2. Bring the system to ready status by performing Weekly Instrument Care and QC (if necessary as indicated by on-screen prompts)
3. Ensure that the sample:
    a. It is not from patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.
    b. Is a 12-15 mm, 2 – 4 mL draw vacuum tube, (as pictured on the system ready screen).
    c. Is a purple top K_2 or K_3EDTA tube.
4. Has sufficient fill volume; 1mL for vacuum tubes.
5. Press "Continue" when the instrument requests the operator to confirm a purple top collection tube was used.
6. Enter your operator ID, a unique patient identifier number (which may be any combination of up to 9 alpha/numeric characters with no more than 2 alpha and 7 numeric characters) and the patient's date of birth.
7. Open the sample door and insert the correct tube adapter into the system (follow on-screen prompts).
8. Follow the on-screen prompts to begin testing
    a. Is not cold to the touch, (follow on-screen instructions)
    b. Is properly mixed (follow on-screen instructions)
9. Insert the sample collection tube into the adapter and close the sample door.
10. Follow any additional on-screen instructions and deliver the results printout to the ordering Clinician.

Time Restrictions

- Whole blood samples stored at room temperature (59 - 77° F or 15 - 25° C) for longer than 8 hours and samples stored refrigerated (36 - 46° F or 2 - 8° C) for longer than 36 hours should not be tested.

Accessories Required (provided)

- Reagent Tray
- Thermal Paper
- Waste Bottle
- Adapters (Green and White)
- Clinician's Quick Guide
- Operator's Quick Guide
- Start Up Quick Guide
- Shutdown Quick Guide
- Power Cord
- Ethernet Cable
- Barcode Reader and Cable
- Regent Tubing
- COIL TUBE SS-10
- Technical Specifications

Materials Required but Not Provided

- Full time and dedicated high speed internet connection
- Clorox Wipes
    - This product is safe for use on the Sysmex XW-100, however, any product with EPA registration number of 67619-12 can be used on the device.
    - This product can be purchased at local grocery or convenience store.
- Towelette or paper towel – (can be purchased at local grocery store)
- Water (Note, any grade of water is acceptable, including tap water)
- Blood collection tubes and other phlebotomy supplies*
- Disposable gloves, lab coat and eye protection*
- Biohazard container*

*These can be purchased through medical supply companies.

Cleanup of spills

1. Put on personal protective equipment; disposable gloves and eye protection.

2. Clean spills from the surface with a new Clorox Wipe. Wipe down the surface area with a different new Clorox Wipe to disinfect.
3. Allow the disinfected areas to sit for at least one minute. Wipe down all disinfected areas with a towelette (or paper towel) moistened with water.
4. Dispose of all cleaning materials in a biohazard container. Allow surfaces to air dry prior to use.
5. Remove gloves and thoroughly wash hands with soap and water after disinfection.

Daily Cleaning and Disinfecting

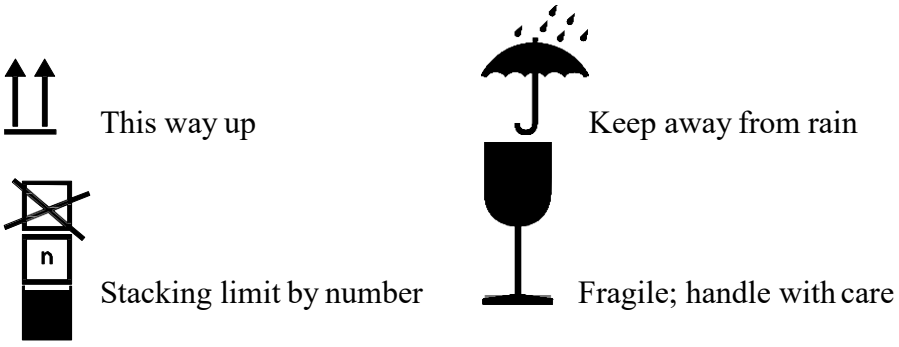
1. Put on personal protective equipment; disposable gloves, eye protection, and lab coat.
2. Using a new Clorox Wipe clean and disinfect the system outer housing, display, exterior of the sample chamber and the white sample adapter used for testing on the XW-100 every day. Wipe down all surface areas with a different new Clorox Wipe to disinfect.
3. Allow the disinfected areas to sit for at least one minute. Wipe down all disinfected areas with a towelette (or paper towel) moistened with water.
4. Dispose of all cleaning materials in a biohazard container. Allow surfaces to air dry prior to use.
5. Remove gloves and thoroughly wash hands with soap and water after disinfection of the device.
6. Daily cleaning and disinfection must be documented. Please refer to Appendix A for a template to document the completion of this activity.

Caution:

The following are signs of deterioration of the device and/or screen covers. If present, please contact Technical Assistance.

- Paint and/or plastic flaking
- Rust
- Hazy screen covers
- Quality control is out of range
- Device lock up

Packaging Symbols



Good Laboratory Practice

Some waived tests have potential for serious health impacts if performed incorrectly. To decrease the risk of erroneous results, the test needs to be performed correctly, by trained personnel and in an environment where good laboratory practices are followed. Some examples of Good Laboratory Practice include:

- Confirm patient identification and test order before collecting patient sample
- Confirm the patient sample was properly collected and handled prior to testing
- Confirm familiarity with the manufacturer's Quick Reference Guide prior to testing
- Report patient results only to authorized persons

For more information regarding Good Laboratory Practice, a free educational booklet and online training is available on the CDC website at https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx

Test Principle

A patient sample is aspirated, measured, diluted with diluent (and Lyse for WBC measurement) then fed into each of two transducer chambers by means of a hydrodynamic focusing nozzle. There are two analysis flows (WBC/HGB and RBC/PLT) that feeds into the WBC and RBC/PLT transducer chambers. The transducer chambers have a minute hole or aperture. Electrodes are mounted on both sides of the aperture chamber through which flows the Direct Current or DC. Blood cells suspended in the diluted sample are injected through the aperture by the hydrodynamic focusing nozzle. The hydrodynamic focusing nozzle is positioned in front of the aperture and in line with the aperture's center. This method improves cell counting accuracy because all blood cells are separated from each other and can only pass through the aperture in one direction one at a time. The analyzer uses DC (direct current) with hydrodynamic focusing for all parameters except hemoglobin which is measured photometrically. Hemoglobin is measured photometrically in the HGB flow cell using a non-cyanide methodology which reduces the presence of hazardous materials in the analyzer waste stream.

When a cell passes through the aperture, it causes a change in the DC resistance that is directly proportional to its size. These resistance changes are captured as electric pulses. The various blood cell counts are calculated by counting the pulses that occur in each cell size category. The analyzer then determines blood cell volume and identifies rare and pathological cells by creating and analyzing histograms of the various cell populations using their respective pulse heights.

With the introduction of the lysing reagent in the WBC transducer chamber, red blood cells are hemolyzed and platelets shrink leaving the WBC membrane in place for counting. The white blood cells are calculated from the particle counts between the LOWER and UPPER discriminator. The optimum position of the LOWER discriminator and UPPER discriminator are between 30 -60 fL and 300 fL, respectively, and are automatically determined by the microcomputer. In the WBC/HGB analysis flow, a sample of blood by passes the WBC transducer chamber and goes to the HGB flow cell for measurement.

In the RBC/PLT transducer chamber, the red blood cells are calculated from the particle counts between the LOWER and UPPER discriminator. The optimum position of the LOWER discriminator and UPPER discriminator are between 25 - 75 fL and 200 - 250 fL, respectively, and are automatically determined by the microcomputer. The platelets are calculated from the particle counts between the LOWER and UPPER discriminator. The optimum position of the

LOWER discriminator and UPPER discriminator are between 2 - 6 fL and 12 - 30 fL, respectively, and are automatically determined by the microcomputer.

Explanation of Flagging System

Blood cells are counted and fall into designated discriminators into histograms. Those cells outside of the outer discriminators or if there is no clear separation between cell types will prompt the flagging system of the device. The flagging system suggests sample error, instrument error or the presence of abnormal samples. Note: Histograms are not available on the printout and are only discussed here to understand the flagging interpretation. Printing of the flags has been simplified for the CLIA waiver environment.

- WBC Histogram – The WBC histogram is discriminated into small, middle and large WBC by 3-part differential method using 4 discriminators. The LOWER discriminator (LD) is automatically determined at an optimum position between 30 and 60 fL. The UPPER discriminator (UD) is fixed at 300 fL, which is used as the monitor for the histogram error. There are two troughs in the histogram that separates the small and middle WBC and the middle and large WBC.
    - LYM# - Lymphocytes are the smallest cells of the 3-part differential and falls between the LOWER discriminator (LD) and the first trough . (LYM% is the ratio of lymphocytes to the WBC count.)
    - Other WBC# - Other WBC are the Monocytes, Eosinophils and Basophils and in size represent the middle cells of the 3-part differential and falls between the first trough and the second trough . (Other WBC% is the ratio of Other WBCs to the WBC count.)
    - NEUT# -- Neutrophils are the largest cells of the 3-part differential and falls between the second trough to the UPPER discriminator (UD). (NEUT% is the ratio of neutrophils to the WBC count.) Cells such as immature granulocytes would fall within this area.

List of WBC Error Flags

Type of Histogram Flag	Description	Probable Sample Cause	Suggested Action
WBC	Relative frequency for LOW discriminator (LD) exceeds the range	Unlysed RBCs, NRBC, large PLT, PLT aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids, fragile WBCs, cryoglobulins, malaria parasites, old sample.	•Retest the same sample. If the retest confirms the flag, send the sample to a reference lab.
WBC DIFF	Lower TROUGH discriminator, that separates the lymphocytes & Other WBC, cannot be determined	Presence of CML or other immature granulocytes, unlysed RBC, aged sample, increased Other WBC (monocytes, eosinophils and/or basophils) population, decreased neutrophil size causing interference in the other populations.	Same as above

WBC DIFF	Higher TROUGH discriminator, the separates the Other WBC and neutrophils, cannot be determined	Presence of CML or other immature granulocytes, increased monocytes, eosinophils, basophils, unlysed RBC, aged samples, increased Other WBC population, decreased neutrophil size causing interference in the other populations.	• Retest the same sample. If the retest confirms the flag, send the sample to a reference lab.
WBC DIFF	Small cell histogram error. Relative frequency for first trough exceeds the range.	Presence of CML or other immature granulocytes, increased monocytes, eosinophils, basophils, unlysed RBC, aged sample.	Same as above
WBC DIFF	Middle cell histogram error. Relative frequency for first trough or second trough exceeds the range.	Presence of CML or other immature granulocytes, increased monocytes, eosinophils, basophils, unlysed RBC, aged sample.	Same as above
WBC DIFF	Large cell histogram error. Relative frequency for second trough exceeds the range.	Presence of CML or other immature granulocytes, increased monocytes, eosinophils, basophils, unlysed RBC, aged sample.	Same as above
WBC	Relative frequency for UPPER discriminator (UD) exceeds the range.	Unlysed RBC, presence of immature WBCs, WBC aggregation, PLT satellite phenomenon, elevated WBC count, hypersegmented neutrophils.	Same as above
WBC/PLT	The particle count equal to or less than the LD exceeds a prescribed range.	Presence of NRBC, increase of large PLT, PLT aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids.	Same as above

List of RBC Error Flags

Type of Histogram Flag	Description	Probable Sample Cause	Suggested Action
RBC	Relative frequency for LOW discriminator (LD) exceeds the range	Presence of fragmented RBC, large PLT, PLT aggregation or micro-erythrocytes, electronic noise.	•Retest the same sample. If the retest confirms the flag, send the sample to a reference lab.
RBC	Relative frequency for UPPER discriminator (UD) exceeds the range	Effects of cold agglutinin, inclusion of WBCs, electronic noise, increased NRBCs	Same as above
RBC	Two or more peaks in the histogram	Effects of anemia treatment or blood transfusions causing the presence of cells of multiple sizes.	Same as above
RBC	Particle distribution width error for 20% frequency with the peak taken as 100%. When the 20% frequency does not cross the histogram two times, this flag is appears.	Significant anisocytosis.	Same as above

List of PLT Error Flags

Type of Histogram Flag	Description	Probable Sample Cause	Suggested Action
PLT	Relative frequency for LOW discriminator (LD) exceeds the range	Effects of cryoglobulins, fragmented RBC or cellular fragments of WBcs, electronic noise.	•Retest the same sample. If the retest confirms the flag, send the sample to a reference lab.
PLT	Relative frequency for UPPER discriminator (UD) exceeds the range	Increase of large PLT, inclusion of fragmented RBCs, precipitation of cryoglobulins, PLT aggregation or agglutination, presence of micro-erythocytes, electronic noise.	Same as above
PLT	Two or more peaks in the histogram	PLT aggregation, low PLT count	Same as above
PLT	Particle distribution width error for 20% frequency with the peak taken as 100%. When the 20% frequency does not cross the histogram two times, this flag is appears.	Inclusion of fragmented RBCs, non-uniformity in PLT size, effects of cryoglobulins.	Same as above

Printing of Results

- It is normal for results not to be displayed. Results are printed only to avoid the possibility of transcription errors.
- Results printouts will list patient ID and DOB, Operator ID and time of test as well as results for each parameter and its appropriate reference range. The printout may have flags which should be interpreted by the Clinician. Clinicians must consult the *XW- 100 Clinician's Quick Guide* in this manual for additional information.
- All results interpretation must be made by the Clinician.

Quality Control

- QC monitors every aspect of analyzer performance by testing QC materials with known levels of each test parameter. For QC to pass, the results generated must fall within acceptable levels for each parameter and at three different levels (Low, Normal, High).
- Note: QC must be performed as follows:
    - Every 8 hours of instrument use
    - When a new lot of reagent is used
    - After completing weekly care
- The system will prompt users when QC is required and will not allow patient samples to be tested until QC is performed.
- If the analyzer screen indicates "QC Check required", simply follow the on-screen prompts and images.
- QC results are recorded internally and are not printed. The instrument stores up to 100 patient and QC results, however the QC results are not retrievable by the CLIA waived operator.

Expected Values

- Results for all tested CBC parameters are reported as quantitative results. Results are additionally flagged as High / Low when they are above or below the reference ranges established for the patient age. Results are additionally flagged as ALERT when they fall below or above the ranges established for the affected parameter.

Reference Intervals – Whole Blood

The following are the Reference Intervals for the XW-100:

Table 1: Pediatric Reference Ranges

PARAMETER	Units	Proposed Pediatric Reference Range (≥2 - <12yrs)	XW-100 Sample Range N=27
WBC	x $10^3/\mu L$	4.8-13.5	5.0-11.2
RBC	x $10^6/\mu L$	4.2-5.4	4.22-5.32
HGB	g/dL	10.5-16.0	11.7-15.1
HCT	%	29.0-48.0	35.4-42.8
MCV	fL	76.0-99.0	78.2-89.3
PLT	x $10^3/\mu L$	163-369	219-345
NEUT#	x $10^3/\mu L$	1.92-8.64	1.90-6.70
LYM#	x $10^3/\mu L$	0.96-7.29	1.8-5.0
Other WBC#	x $10^3/\mu L$	0-2.27	0.10-1.70
NEUT%	%	35.0-76.0	36.0-71.4
LYM%	%	20.0-54.0	22.3-51.3
Other WBC%	%	0-19.0	0.7-18.3

Note: Central 95% Confidence Interval not available due to insufficient sample size (<40).

Table 2: Adolescent Reference Ranges

PARAMETER	Units	Proposed Adolescent Reference Range (≥12 - <21yrs)	XW-100 Sample Range and Central 95% Interval N=96
WBC	x $10^3/\mu L$	4.8-10.80	4.80-10.60 (4.80,10.46)
RBC	x $10^6/\mu L$	4.2-6.10	4.45-5.75 (4.46,5.69)
HGB	g/dL	12.0-18.0	12.3-17.1 (12.5, 16.6)
HCT	%	37.0-52.0	37.0-50.1 (37.4, 49.4)
MCV	fL	80.0-99.0	81.0-96.0 (82.1, 94.0)
PLT	x $10^3/\mu L$	163-369	179-359 (183,355)
NEUT#	x $10^3/\mu L$	1.92-8.64	2.40-7.90 (2.60,7.36)
LYM#	x $10^3/\mu L$	0.4-3.9	0.9-4.1 (1.1, 3.2)
Other WBC#	x $10^3/\mu L$	0.0-2.0	0.1-1.7 (0.1,1.3)
NEUT%	%	40.0-80.0	46.4-78.8 (47.0, 77.3)
LYM%	%	15.0-40.0	16.9-39.9 (17.2, 39.4)
Other WBC%	%	0.0-19.0	0.9-20.7 (1.7,18.6)

Table 3: Adult Reference Ranges

Parameters	Units	Adult Reference Range (≥21yrs) (N=116)	Adult Male Range And 95% CI (N=52)	Adult Female Range And 95% CI (N=64)
WBC	x $10^3/\mu L$	3.9-10.4	4.5-9.9 (4.5,9.7)	4.1-9.7 (4.2,9.4)
RBC	x $10^6/\mu L$	3.71-5.52	4.02-6.01 (4.07,5.91)	3.95-5.61 (3.96,5.27)
HGB	g/dL	10.9-16.7	12.4-17.3 (12.5,17.3)	11.4-16.0 (11.5,15.4)
HCT	%	32.5-49.4	37.8-50.7 (37.9,50.6)	34.9-47.9 (35.1,46.9)
MCV	fL	82.5-98.0	80.0-94.9 (81.3,94.6)	80.9-94.9 (80.9,94.8)
PLT	x $10^3/\mu L$	148-382	164-343 (165,338)	185-369 (187,348)
NEUT#	x $10^3/\mu L$	2.2-7.1	2.4-5.9 (2.4,5.9)	2.6-7.4 (2.6,7.4)
LYM#	x $10^3/\mu L$	0.9-3.4	1.0-3.2 (1.0,3.1)	1.2-4.1 (1.2,3.9)
Other WBC#	x $10^3/\mu L$	0.2-1.2	0.1-1.7 (0.1,1.6)	0.1-1.7 (0.1,1.6)
NEUT%	%	46.4-76.9	44.1-71.1 (44.8,70.8)	37.2-71.1 (38.8,70.8)
LYM%	%	14.7-45.9	17.4-50.9 (18.4,48.9)	19.6-56.7 (20.8,52.5)
Other WBC%	%	3.2-16.9	1.7-18.3 (2.1,17.9)	1.4-14.3 (2.3,13.9)

Performance Characteristics

Table 4 Performance/ specifications of the Sysmex XW-100	
Ambient temperature	15°C-25°C (59°F-77°F)
Operating environment (relative humidity)	30%-85%
Storage conditions (transportation)	Drained and packed in special box
Power supply	100-240 VAC (+ 10%)
Power consumption	150 VA or less
Protection type	250V 3.15A fuse protected
Display range Acceptance background value Reportable range (Limit of Quantitation, LoQ) The actual amount of an analyte that can be reliably detected (Limit of Detection, LoD) and at which total error meets the requirements for accuracy that is acceptable for clinical use.	No results are displayed WBC 0.3 (x $10^3/\mu L$) RBC 0.02 (x $10^6/\mu L$) HGB 0.1 (g/dL) PLT 10 (x $10^3/\mu L$) WBC 1.0-63.2 x $10^3/\mu L$ RBC 0.3-7.0 x $10^6/\mu L$ HGB 0.1-25.0 g/dL HCT 10.0%-60.0% MCV N/A* PLT 10.0-999 x $10^3/\mu L$ LYM% 0.0-100.0% NEUT% 0.0-100.0% Other WBC% 0.0-100.0% LYM# 0.0-63.2 x $10^3/\mu L$ NEUT# 0.0-63.2 x $10^3/\mu L$ Other WBC# 0.0-63.2 x $10^3/\mu L$
Analysis time Accuracy (against an alternate method) Precision (repeatability)	Approximately 148 seconds WBC within $\pm$ 3% or $\pm$ 0.2 x $10^3/\mu L$ RBC within $\pm$ 2% or $\pm$ 0.03 x $10^6/\mu L$ PLT within $\pm$ 5% or $\pm$ 10 x $10^3/\mu L$ WBC when $\geq$4.0 x $10^3/\mu L$; 3.5%CV or less RBC when $\geq$3.0 x $10^6/\mu L$; 2.0%CV or less HGB 1.5% or less HCT 2.0% or less MCV 2.0% or less PLT when $\geq$100 x $10^3/\mu L$; 6.0%CV or less LYM% 15.0% or less NEUT% 15.0% or less Other WBC% when $\geq$12%; 30.0% or less LYM# 15.0% or less NEUT# 15.0% or less Other WBC# when $\geq$1.0 x $10^3/\mu L$; 30.0%CV or less

Linearity (when RBC < 7.00 x 10^6/µL)	WBC 1.0-9.9 x 10^3/µL; ± 0.3 x 10^3/µL or less 10.0-99.9 x 10^3/µL; ± 3% or less RBC 0.3-0.99 x 10^6/µL; ± 0.03% x 10^6/µL or less 1.00-7.00 x 10^6/µL; ± 3% or less HGB 0.1-10.0 g/dL; ± 0.2 g/dL or less 10.0-25.0 g/dL; ± 2% or less HCT 10.0%-33.3%; ± 1.0 HCT% or less 33.3%-60.0%; ± 3% or less PLT 10.0-199 x 10^3/µL; ± 10 x 10^3/µL or less 200-999 x 10^3/µL; + 5% or less
Carryover (whole blood analysis mode)	WBC 3% or less RBC 1.5% or less HGB 1.5% or less PLT 5% or less
Aspired blood volume	Approximately 15µL
Data capacity	100 test cycles (patients, controls, blanks)
QC	Three levels of QC must be performed as follows: o Every 8 hours of instrument use o When a new lot of reagent is used o After completing weekly care The system will prompt users when QC is required and will not allow patient samples to be tested until QC is performed.

* "NA" means Not Applicable.

Method Comparison

Correlation Coefficient and Estimation of Bias was assessed by comparison of the results from the XW-100 and the pocH-100*i*. The study was conducted with standard laboratory operators for the pocH-100*i* and POC operators in a POC setting for the XW-100 at 3 different clinical sites. The estimation of the difference was determined as described in CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples. When specimens covering the measuring range are analyzed by both the XW-100 and the pocH-100*i* the XW-100 meets r-value and bias limits as defined in the table below.

Table 5 XW-100 Estimation of Bias and Correlation Coefficient Limits Summary

Parameter	Units	N	Range	r	r-value Limit	Mean Difference (Mean Bias)	Mean % Difference (Mean % Bias)	Bias Limit
WBC	$10^3/\mu L$	390	0.2 to 63.2	0.995	≥ 0.95	0.09	1.4%	± 15%
RBC	$10^6/\mu L$	391	1.49 to 8.11	0.995	≥ 0.95	-0.01	-0.3%	± 6%
HGB	g/dL	391	3.8 to 23.0	0.994	≥ 0.95	0.06	0.6%	± 7%
HCT	%	391	12.4 to 68.2	0.991	≥ 0.95	-0.10	-0.2%	± 6%
MCV	fL	391	71.9 to 108.1	0.965	≥ 0.90	0.06	0.1%	± 7%
PLT	$10^3/\mu L$	391	11 to 1222	0.994	≥ 0.95	-0.22	0.2%	± 25%
NEUT	%	316	24.3 to 97.6	0.968	≥ 0.90	-0.24	-0.3%	± 15%
LYMPH	%	316	1.5 to 67.4	0.993	≥ 0.90	0.16	1.5%	± 15%
Other WBC	%	316	0.6 to 48.9	0.765	≥ 0.60	0.08	11.9% (median 1.0%)	± 15%

Precision (Repeatability)

Short-term imprecision of the XW-100 instrument parameters was evaluated by POC operators in the POC setting in accordance with CLSI EP5-A2 approved guideline using ten replicates of residual whole blood at 3 different clinical sites. The XW-100 meets CV% limits as defined in the table below.

Table 6		**Precision Repeatability Summary**									
XW-100 Whole Blood Repeatability		**Site 1**			**Site 2**			**Site 3**			**CV% Limit**
Measurand	**Sample**	**Mean**	**SD**	**CV%**	**Mean**	**SD**	**CV%**	**Mean**	**SD**	**CV%**	**CV%**
WBC ($\times 10^3/\mu L$)	1	1.47	0.09	6.45	1.56	0.05	3.31	1.54	0.10	6.27	≤ 8.0 (WBC < 4.0 $\times 10^3/\mu L$)
	2	4.94	0.13	2.56	5.13	0.08	1.60	5.14	0.11	2.09	≤ 3.5 (WBC ≥ 4.0 $\times 10^3/\mu L$)
	3	50.29	0.38	0.76	50.97	0.39	0.76	52.06	0.59	1.13	≤ 3.5 (WBC ≥ 4.0 $\times 10^3/\mu L$)
RBC ($\times 10^6/\mu L$)	1	1.76	0.02	0.97	1.86	0.02	1.05	1.25	0.01	1.00	≤ 2.0 (RBC ≥ 3.00 $\times 10^6/\mu L$)
	2	4.45	0.03	0.69	4.49	0.03	0.72	4.48	0.02	0.55	≤ 2.0 (RBC ≥ 3.00 $\times 10^6/\mu L$)
	3	10.74	0.05	0.49	10.84	0.12	1.11	10.80	0.08	0.70	≤ 2.0 (RBC ≥ 3.00 $\times 10^6/\mu L$)
HGB (g/dL)	1	3.58	0.04	1.18	3.69	0.03	0.86	1.60	0.00	0.00	≤ 1.5
	2	8.78	0.04	0.48	8.70	0.05	0.54	8.81	0.06	0.64	≤ 1.5
	3	11.72	0.09	0.78	11.60	0.07	0.57	11.82	0.06	0.54	≤ 1.5
	4	21.22	0.13	0.62	21.21	0.14	0.65	21.59	0.09	0.41	≤ 1.5
HCT (%)	1	12.14	0.12	0.97	12.76	0.15	1.18	9.24	0.13	1.46	≤ 2
	2	31.26	0.23	0.74	31.59	0.22	0.69	31.73	0.17	0.54	≤ 2
	3	47.14	0.40	0.86	48.58	0.39	0.79	48.53	0.22	0.46	≤ 2
	4	76.17	0.34	0.45	76.77	0.74	0.96	76.77	0.49	0.64	≤ 2
PLT ($\times 10^3/\mu L$)	1	36.1	3.31	9.18	38.2	1.93	5.06	35.8	1.69	4.71	≤ 10 (PLT < 100 $\times 10^3/\mu L$)
	2	210.7	12.96	6.15	214.7	12.37	5.76	94.2	4.69	4.97	≤ 6 (PLT ≥ 100 $\times 10^3/\mu L$)
	3	899.3	12.65	1.41	944.3	16.80	1.78	973.2	20.20	2.08	≤ 6 (PLT ≥ 100 $\times 10^3/\mu L$)
MCV	1	68.40	0.29	0.43	68.46	0.36	0.53	69.00	0.27	0.39	<2.0%
	2	70.93	0.11	0.15	70.37	0.14	0.20	70.83	0.16	0.23	<2.0%
	3	73.31	0.13	0.18	74.05	0.60	0.81	73.74	0.60	0.82	<2.0%

Table 6 (continued) Precision RepeatabilitySummary											
XW-100 Whole Blood Repeatability		**Site 1**			**Site 2**			**Site 3**			**CV% Limit**
Measurand	**Sample**	**Mean**	**SD**	**CV%**	**Mean**	**SD**	**CV%**	**Mean**	**SD**	**CV%**	**CV%**
LYMPH%	1	27.49	0.84	3.04	27.99	0.95	3.38	27.80	1.18	4.26	<15.0%
	2	35.56	2.91	8.19	35.35	2.78	7.87	35.71	1.28	3.57	<15.0%
	3	47.99	1.53	3.18	50.56	0.86	1.71	50.99	0.49	0.95	<15.0%
Other WBC%	1	9.23	1.06	11.52	8.21	2.31	28.15	8.04	1.77	21.96	<30.0% (Other WBC>12%)
	2	11.71*	1.28	10.97	6.74	1.59	23.62	8.80*	0.88	10.05	<30.0% (Other WBC≥12%)
	3	14.75	2.66	18.05	14.84	2.18	14.67	13.00	1.90	14.65	<30.0% (Other WBC≥12%)
NEUT%	1	49.69	3.10	6.25	49.81	4.13	8.29	51.29	2.70	5.26	<15.0%
	2	63.28	1.08	1.70	63.80	2.02	3.17	64.06*	2.59	4.04	<15.0%
	3	62.53*	1.14	1.82	58.24*	2.99	5.13	65.34*	0.97	1.48	<15.0%
LYMPH#	1	1.36	0.08	6.20	1.44	0.05	3.59	1.44	0.07	4.86	<15.0%
	2	3.22	0.06	1.96	4.63	0.13	2.70	4.69	0.10	2.12	<15.0%
	3	12.94	0.22	1.72	13.08	0.29	2.24	13.46	0.19	1.41	<15.0%
Other WBC#	1	0.21	0.06	27.03	0.41	0.10	24.25	0.42*	0.08	19.74	<30.0% (Other WBC≥1.0)
	2	1.30*	0.24	18.84	0.23	0.05	21.00	0.21	0.03	15.06	<30.0% (Other WBC≥1.0)
	3	5.90*	0.65	10.95	5.97*	1.22	20.38	4.58*	0.48	10.58	<30.0% (Other WBC≥1.0)
NEUT#	1	0.75	0.07	9.43	0.78	0.10	13.24	0.78	0.04	5.41	<15.0%
	2	3.13	0.13	4.00	3.28	0.11	3.46	3.27*	0.17	5.08	<15.0%
	3	31.47*	0.62	1.96	7.98	0.26	3.28	34.00*	0.50	1.48	<15.0%

*Denotes less than 10 results available from the 10 repeats.

Precision (Reproducibility)

Precision (reproducibility) was assessed by using 3 levels of control material tested by POC operators in duplicate twice each day for 20 days using a single lot of control material at 3 different clinical sites. The results were determined by analysis of variance (ANOVA) in accordance with CLSI EP 05-A2 approved guideline and meet the acceptance criteria as defined in the table below.

Table 7 XW-100 Reproducibility Summary

XW-100 Reproducibility Summary XW QC CHECK				Within Run		Between Run		Between Day		Between Site		Total		Acceptance Criteria
Measurand	**Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**%CV**
WBC	Low	256	2.904	0.086	2.96	0.041	1.41	0.000	0.00	0.042	1.46	0.104	3.59	≤ 12.0%
	Normal	256	6.946	0.193	2.77	0.000	0.00	0.072	1.03	0.085	1.22	0.222	3.20	≤ 9.0%
	High	256	18.12	0.295	1.63	0.000	0.00	0.141	0.78	0.254	1.40	0.414	2.28	≤ 7.5%
RBC	Low	256	2.392	0.028	1.18	0.005	0.22	0.004	0.16	0.033	1.38	0.044	1.84	≤ 6.5%
	Normal	256	4.482	0.037	0.83	0.020	0.45	0.030	0.68	0.058	1.30	0.078	1.74	≤ 5.5%
	High	256	5.324	0.047	0.89	0.019	0.35	0.028	0.52	0.065	1.21	0.087	1.63	≤ 5.5%
HGB	Low	256	6.332	0.091	1.44	0.032	0.51	0.000	0.00	0.029	0.45	0.101	1.59	≤ 6.0%
	Normal	256	13.26	0.191	1.44	0.000	0.00	0.093	0.70	0.128	0.97	0.248	1.87	≤ 5.0%
	High	256	17.25	0.142	0.82	0.047	0.27	0.085	0.49	0.180	1.04	0.249	1.44	≤ 5.0%
HCT	Low	256	18.67	0.224	1.20	0.089	0.48	0.135	0.72	0.202	1.08	0.342	1.83	≤ 8.0%
	Normal	256	38.27	0.325	0.85	0.203	0.53	0.341	0.89	0.375	0.98	0.635	1.66	≤ 7.0%
	High	256	47.94	0.416	0.87	0.232	0.48	0.353	0.74	0.447	0.93	0.743	1.55	≤ 7.0%
MCV	Low	256	78.05	0.226	0.29	0.158	0.20	0.553	0.71	0.183	0.23	0.644	0.83	≤ 7.0%
	Normal	256	85.39	0.209	0.24	0.179	0.21	0.473	0.55	0.240	0.28	0.597	0.70	≤ 5.5%
	High	256	90.06	0.221	0.25	0.230	0.26	0.456	0.51	0.218	0.24	0.598	0.66	≤ 5.5%

Table 7 (continued) **XW-100 Reproducibility Summary**

XW-100 Reproducibility Summary XW QC CHECK				Within Run		Between Run		Between Day		Between Site		Total		Acceptance Criteria
Measurand	**Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**%CV**
PLT	Low	256	56.80	2.759	4.86	0.000	0.00	1.454	2.56	1.079	1.90	3.299	5.81	≤ 25.0%
	Normal	256	222.5	5.890	2.65	1.259	0.57	3.118	1.40	4.920	2.21	8.379	3.77	≤ 14.0%
	High	256	507.1	9.535	1.88	1.593	0.31	4.705	0.93	12.305	2.43	16.340	3.22	≤ 11.0%
LYM#	Low	256	0.712	0.040	5.62	0.023	3.16	0.000	0.00	0.008	1.09	0.047	6.54	≤ 24.5%
	Normal	256	2.168	0.097	4.46	0.000	0.00	0.040	1.85	0.007	0.32	0.105	4.84	≤ 16.0%
	High	256	6.404	0.144	2.24	0.029	0.45	0.000	0.00	0.163	2.55	0.219	3.42	≤ 10.5%
Other WBC#	Low	254	0.259	0.061	23.52	0.000	0.00	0.007	2.85	0.008	3.11	0.062	23.89	≤ 76.8%
	Normal	254	0.689	0.104	15.08	0.033	4.75	0.000	0.00	0.023	3.38	0.111	16.16	≤ 23.2%
	High	256	2.763	0.218	7.90	0.000	0.00	0.053	1.92	0.012	0.42	0.225	8.14	≤ 12.8%
NEUT#	Low	254	1.933	0.094	4.87	0.018	0.92	0.010	0.50	0.024	1.22	0.099	5.13	≤ 16.5%
	Normal	254	4.089	0.170	4.15	0.000	0.00	0.047	1.14	0.050	1.22	0.183	4.47	≤ 12.0%
	High	256	8.951	0.254	2.84	0.000	0.00	0.076	0.85	0.083	0.92	0.278	3.11	≤ 10.0%
LYM%	Low	256	24.58	1.012	4.12	0.382	1.56	0.000	0.00	0.032	0.13	1.082	4.40	≤ 15.5%
	Normal	256	31.18	0.834	2.67	0.000	0.00	0.221	0.71	0.263	0.84	0.902	2.89	≤ 9.5%
	High	256	35.35	0.557	1.58	0.286	0.81	0.000	0.00	0.423	1.20	0.756	2.14	≤ 7.0%
Other WBC%	Low	254	8.875	1.880	21.18	0.000	0.00	0.000	0.00	0.000	0.00	1.880	21.18	≤ 48.0%
	Normal	254	9.915	1.416	14.28	0.715	7.21	0.000	0.00	0.241	2.43	1.604	16.18	≤ 22.0%
	High	256	15.25	1.175	7.70	0.000	0.00	0.296	1.94	0.000	0.00	1.211	7.94	≤ 12.4%
NEUT%	Low	254	66.56	2.140	3.22	0.000	0.00	0.358	0.54	0.000	0.00	2.170	3.26	≤ 7.5%
	Normal	254	58.90	1.635	2.78	0.411	0.70	0.000	0.00	0.052	0.09	1.687	2.86	≤ 6.5%
	High	256	49.40	1.148	2.32	0.000	0.00	0.195	0.39	0.388	0.78	1.227	2.48	≤ 6.0%

Note: Some QC runs did not report results for all parameters (N < 256).

Table 8	**Components of the Sysmex XW-100**
Component	**Purpose**
1. XW pack L	1. Lyses the RBCs allowing HGB and WBC measurement.
2. XW pack D	2. Dilutes sample to bring cell concentrations into the measureable range.
3. XW QC CHECK	3. Evaluates the accuracy and precision of the XW-100 analyzer. It is not intended for calibration of the analyzer.

Cybersecurity Considerations for IT Coordinators:

During operation, the XW-100 system requires access to the Sysmex SNCS server via broad band internet. For cybersecurity reasons Sysmex recommends the XW-100 be connected to the internet via a firewall protected Large Area Network (LAN) with appropriate anti- malware software installed. In order to connect to the Sysmex SNCS server the firewall must be configured to allow Dynamic Host Configuration Protocol (DHCP) and outbound communication via port 443 Secure Socket Layer (SSL) access to the URL address *pochi-sncs- ws.sysmex.com*.

*Note: If there are problems with connecting to SNCS, contact TAC Services (1-800-779-7639).

Distributor

- The XW-100 is sold and serviced by

  Sysmex America Inc.
  577 Aptakisic Road
  Lincolnshire, IL 60069

Appendix A

Month/Year _____

XW-100 Cleaning Log

Serial Number _____

Daily Care

Task	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean and Disinfect Analyzer																															
Initials																															

Miscellaneous

Task	Date/Initials

Task	Date/Initials

Reviewed

Print Name _____ Signature _____ Date _____