National Standard Operating Procedure for Sysmex XQ-Series (XQ-520) Automated Hematology Analyzer

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Table of Contents:

Acronyms	4
1. Purpose	5
2. Scope	5
3. Definitions	5
4. Procedure	5
5. Responsibilities	11
6. Document History and Version Control	12
7. References	13
8. Annexes	14

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Acronyms:

Acronym	Definition
SOP	Standard Operating Procedure
MOH	Ministry of Health
IFU	Instructions for Use
DC	Direct Current (used in DC Impedance method)
IP Message	Interpretive Program message (Analyzer Flag/Comment)
WBC	White Blood Cell
RBC	Red Blood Cell
HGB	Hemoglobin
PLT	Platelet
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
NEUT, LYMPH,	Neutrophil, Lymphocyte
MXD	Mixed Cell Group (Monocytes, Eosinophils Basophils)
AMR	Analytical Measurement Range, Linearity Range or Interval **Measuring Interval (Reportable Range)**
RT	Room Temperature
W-LCC	White-Large Cell Count
W-SCC	White-Small Cell Count
W-MCC	White-Medium Cell Count

1. **Purpose**

This document describes the procedure for the safe and correct operation of the Sysmex XQ-520 XQ-Series Automated Hematology Analyzer. This procedure provides instruction for the classification and quantification of parameters in whole blood as an aid to diagnosis of patient populations found in clinical laboratories.

2. **Scope**

This document is applicable for all medical laboratories under MOH and other collaborative governmental and non-governmental health institutions. The instrument is intended to be used by **properly trained personnel** (Medical Laboratory Technicians).

3. **Definitions**

3.1 Complete Blood Count (CBC): A standardized hematological test that quantitatively measures the cellular components of blood, including hemoglobin concentration, red blood cell count and indices, white blood cell count (with or without differential), and platelet count, performed using validated automated hematology analyzers in accordance with ICSH recommendations.

3.2 Differential white cells count (DIFF): A blood test that measures the percentage or number of each of the five types of white blood cells (neutrophils, lymphocytes, monocytes, eosinophils and basophils).

3.3 Quality control (QC): the process of monitoring a test during its development to ensure it meets predefined standards and customer expectations.

4. **Procedure**

4.1 Clinical background:

Complete Blood Count (CBC) is an essential and widely used hematological test that quantitatively assesses cellular components of blood including red blood cells, white blood cells, and platelets. The CBC reflects the functional status of bone marrow and related haematopoietic tissues.

CBC parameters are critical for diagnosing and monitoring diseases such as anemia, infections, inflammation, hematologic malignancies, and systemic disorders. Key red cell indices (MCV, MCH, MCHC) provide insights into red cell size and hemoglobin content, while white blood cell differentials assist in identifying immune status and

hematologic abnormalities. Variations outside reference ranges guide further clinical evaluation and intervention.

4.2 Principle:

The Sysmex XQ-520 is a blood count analyzer for *in vitro* diagnostic use.

Component Measured	Principle of Technology	Description
WBC, RBC, PLT	DC Impedance Method (Direct Current)	Provides quantitative, identification, and existence ratio analysis of blood components. Cells passing through an aperture generate electric pulses proportional to their volume.
HGB	Non-cyanide HGB analysis method (Colorimetric method)	Provides quantitative analysis of HGB. A lysing reagent releases haemoglobin, which is oxidized to methaemoglobin. The concentration is determined by spectrophotometry at 555 nm, which measures the light absorption of the complexes.
3-Part Differential (NEUT, LYMPH, MXD)	DC Impedance Method & Lysis	Achieved by using a lysing reagent to cause different degrees of shrinkage in WBCs. Cells are then classified by their resultant volume into three categories based on trough discriminators on the WBC histogram.

4.3 Pre-Analytical Stage

4.3.1 Sample Type and Collection

Requirement	Detail
Sample Type	Whole blood
Anticoagulant	EDTA 2K or EDTA 3K
Minimum Volume (Closed Tube)	The instrument can analyze small volume samples. However, the minimum required aspiration volume for a stable result in Whole Blood (WB) mode is generally ~100 μL.
Mixing	Blood samples must be gently and thoroughly mixed by inverting the tube a minimum of 8 times just prior to aspiration.

4.3.2 Sample Stability and Storage

Parameter	Stability Time	Storage Temperature
WBC, RBC, HGB, PLT	24 hours after blood collection	15 - 25 °C (Room Temperature)
Note	Samples stored in a refrigerator (2-8 °C) for 7 days. It must be warmed to room temperature and properly mixed before analysis.	

4.3.3 Criteria for Unacceptable Samples and Action

Unacceptable Condition	Potential Impact/Interference	Follow-up Action
Clots/Fibrin	Can cause inaccurate counts, block apertures, and lead to erroneous IP Messages (flags).	Reject Sample. Collect a new sample (if possible). If a new sample is not possible, document the issue and request a manual review.
Short Sample/Wrong Ratio	Wrong ratio of blood to EDTA can cause cell shrinkage or swelling, affecting MCV, HCT, and MCH.	Reject Sample. Collect a new sample with the correct blood volume.
Extreme Lipemia or Icterus	Can interfere with the HGB measurement (turbidity) and trigger flags.	If flagged, confirm with visual inspection. Manual processing (e.g., plasma blanking if available) or alternative testing may be required per lab SOP.
Improperly Mixed	Inaccurate results, especially for PLT and differential.	Gently re-mix immediately (minimum 8 inversions) and re-analyze.

4.3.4 Consumables, Materials, and Reagents

All reagents and cleaning agents used must be **genuine Sysmex reagents** designed for the XQ-Series to ensure proper instrument function and accurate results.

Item Type	Product Name (Example/Type)	Purpose
Diluent	CELLPACK	Diluent and sheath fluid for cell counting and sizing (RBC, PLT, WBC).
Lysing Agent	STROMATOLYSER-WH	Lysing agent for RBCs to enable WBC count and HGB measurement. Also stabilizes WBC for differential analysis.
Cleaning Agent	CELLCLEAN	For instrument maintenance and cleaning procedures.
Control Material	E-CHECK (or equivalent XQ control blood)	Quality control material used to verify the analyser's performance and accuracy.
Sample Tubes	EDTA 2K/3K Vacuum Tubes	For primary blood sample collection.
Other Materials	Printer paper, fuses, sample tube holders	General operation and maintenance consumables.

4.3.5 Safety Precautions

1. **Wear PPE:** Always adherence to universal precaution, wear adequate **personal protective equipment**, such as protective gloves, a protective mask, protective eyewear, and a lab coat.
2. **Biohazard:** Treat all blood samples, reagents, and waste materials as **potentially infectious material** (biohazards).
3. **Decontamination:** Decontamination of the instrument's outer surfaces should be performed immediately after contamination or in advance of service.

4.3.6 System Start-up (Daily)

1. **Inspection:** Check the connection of tubes and cables, check for bent tubes, and remove any objects on top of the instrument. Ensure waste fluid is discarded from the waste container.
2. **Power On:** Press the **Main Power Switch** (G symbol).
3. **Self-Test:** The instrument automatically performs a **Self-Test** and **Background Check**.
4. **Status Check:** Confirm the instrument status light is illuminated in **green (Ready)** or **orange (Warning)** before proceeding.

4.3.7 Internal Quality Control (QC) Analysis

1. **Lot Registration (New Lot):**
   - Connect external media (e.g., USB memory stick, without a password lock feature) containing the assay file to the USB port.
   - Touch [QC] and then [QC file].
   - Touch [Read assay file], select the file, and touch [OK].
2. **QC Measurement:**
   - Gently and thoroughly mix the QC material.
   - Place the QC tube in the sample tube holder.
   - Press the Manual Analysis Start Switch.
3. **Review:** Check the results on the Levey Jennings [QC chart] screen. If an error *[Control blood has expired]* occurs, use new material and register the lot.

4.4 Analytical Stage

4.4.1 Sample Analysis (Manual Aspiration)

1. Sample Preparation: Gently invert the blood sample tube a minimum of 8 times to ensure proper mixing.
2. Mode Check: Confirm the instrument is set to Manual analysis mode.
3. Aspiration:
   - Open the sample tube cap.
   - Place the sample tube in the holder.
   - Press the Manual Analysis Start Switch (blue button on the unit).
4. Completion: The sampler status LED blinks green during analysis and turns OFF when analysis is complete. Remove the sample tube.

4.4.2 Data Review, Reporting, and Flagging

- **Technical Data Review:**
  1. After measurement, review the complete results screen, including all parameters (WBC, RBC, HGB, PLT, etc.).
  2. Verify that all values are within the display reference, delta and AMR ranges and that the sample ID is correct.

- **Interpretive Program (IP) Messaging/Flagging:**
  1. Pay close attention to all IP messages (flags) generated by the analyzer (e.g., 'WBC Abn Scatter gram', 'PLT Clump', 'NRBC', 'Atypical Lympho?').
  2. Required Follow-up Actions (Refer to XQ-Series Flagging Guide):
     - Morphological/Flagging Review: If a DIFF flag or abnormal cell flag is present, a manual blood film review (microscopic differential count) is mandatory.
     - High/Low Values: Investigate samples with critical/alert values (refer to the Critical Value SOP).
     - Rerun: Rerun samples with common interference flags (e.g., 'PLT Clump') after RT warming /mixing, or by performing an alternate count method (e.g., PLT-O if available).

- **Result Validation and Reporting:**
  1. Once results are verified (including any mandatory manual reviews), validate the results in the LIS/LIMS.
  2. Report results to the authorized clinician according to the laboratory's Critical Value SOP, if applicable.

- **Brief Results interpretation and validation**
  1. Review: Review analysis data on the [Sample explorer] or [Data browser] screens.
  2. Negative Results: A specimen is judged NEGATIVE when no predefined abnormalities or IP messages (flags) are present. These results are generally reported without review.
  3. Positive/Error Results:
     - A POSITIVE judgment is generated when an IP message (flag) is present.
     - POSITIVE or ERROR judgments indicate the possibility of a sample abnormality.
     - A Data error mark [!] appears if an analysis value exceeds the critical value.
     - These results must be reviewed carefully and may require further examination in accordance with the laboratory SOP.

4.5 Routine Cleaning and Shutdown (Daily)

1. Requirement: Shutdown must be performed after finishing analysis work for the day, or at least once every 24 hours.
2. Procedure:
   - Ensure the instrument status is green or orange.
   - In the main menu, touch [Shutdown].
   - Select the checkbox to shut down after routine cleaning.
   - The Routine Cleaning cycle runs automatically and takes approximately 10 minutes.
   - The instrument will power off or perform a final background check upon completion.

4.6 Limitations of the Sysmex XQ-520 Analyzer:

Limitation/Technology Constraint	Description of Issue	Action Required for Technician
Limited Differential	The analyzer provides only a 3-part differential (NEUT, LYMPH, MXD). The MXD (Mixed Cell Group) is composed of Monocytes, Eosinophils, and Basophils, which are not individually differentiated.	Must perform a manual differential count and blood smear review if a differential abnormality is suspected, or if an IP Message (e.g., *WBC Abn Dst*) is triggered.
Interference: NRBCs	Nucleated Red Blood Cells (NRBCs) are resistant to the lysing reagent and are counted in the WBC channel, leading to a falsely elevated WBC count.	If NRBCs are suspected (or a specific NRBC flag is present in higher-end models/manual review), the result must be corrected manually based on the visual blood smear count.
Interference: RBC/PLT Discrimination	Giant Platelets (abnormally large PLTs) may be mistakenly counted in the RBC range, leading to a falsely low PLT count. Conversely, small red cells or RBC fragments may be counted as PLTs, leading to a falsely high PLT count.	Review the PLT and RBC histograms. If a histogram separation abnormality is flagged, verify with a blood smear review or an alternate method.
Interference: HGB Turbidity	Extreme levels of Lipemia (fat) or Icterus (bilirubin) in the sample can cause turbidity, interfering with the HGB Colorimetric Measurement.	The analyzer may flag *Turbidity/HGB Interf?*. The technician should confirm visually. Follow lab SOP, which often requires an alternative HGB measurement or special correction (e.g., plasma blanking if available).
Non-Linear Results	Results falling outside the instrument's Measuring Interval (linearity limits) are not guaranteed to be accurate.	The result will display an Error Flag ([!]). The technician must dilute the sample and re-analyze it to obtain a result within the Measuring Interval before calculation and reporting.
Sample Storage/Stability	Key parameters (WBC, RBC, HGB, PLT) are stable for 24 hours at 15-25 °C. Analysis of samples outside this window may yield inaccurate results.	If the sample is older than 24 hours, follow the lab's policy: reject the sample or perform analysis with a disclaimer regarding time-dependent parameter degradation.
Clots in Sample	Presence of microscopic or macroscopic clots can cause **low cell counts** (due to cell consumption in the clot) and may cause a **blockage** in the fluidic pathway (aperture clog).	**Reject the sample.** Do not attempt to run clotted samples. Collect a new, properly mixed sample.

5. Responsibilities

1. Laboratory Program committee:
    - Ensure that document is approved by ministry of Health and distributed to all institutions
2. Task force creating the document:
    - Ensure that the document is in accordance with Ministry of Health guidelines and is evidence based
    - Ensure that the document is sent to the relevant individuals in different health institutions for review
    - Ensure that the document is modified after receiving relevant feedback from reviewers
    - Ensure that the document is updated where appropriate
3. Laboratory Head/ supervisor
    - Review the document and provide feedback where appropriate
    - Ensure that local standard operating procedures are in line with document
    - Ensure that all staff are trained and adhere to the document
4. Technical staff
    - Be familiar with this document and adhere to it where applicable

6. Document History and Version Control

Version	Description	Review Date
1	Initial Release	August 2031

7. References

Title of Book/Journal/Articles/Website	Author	Year of Publication/Revision
Instructions for Use (IFU): XQ-520 XQ-Series Automated Hematology Analyzer	Sysmex Corporation	03/2024 (Document Version 3.0)
Quick guide: XQ-520 Automated haematology analyser	Sysmex	October 2024 (Version 1.0)
XQ-Series flagging guide (Measurement Principle and IP Messages)	Sysmex Europe SE	December 2022 (Version 1.0)
Ministry of Health SOP Template	Ministry of Health	[Template Date]

8. Annexes

Annex A: XQ-520 Reportable Parameters

The instrument reports the following parameters in Whole Blood:

Analysis Channel	Parameters
WBC	WBC, NEUT# (W-LCC), LYMPH# (W-SCC), MXD# (W-MCC), NEUT% (W-LCR), LYMPH% (W-SCR), MXD% (W-MCR)
RBC/PLT	RBC, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, PDW, MPV, P-LCR, PCT
HGB	HGB

Annex B: WBC IP Messages (Flags)

IP Message	Type	Meaning
WBC Abn Distribution (WBC Abn Dst)	Abnormal	Abnormal WBC particle size distribution (e.g., due to flags like [WL], [WU], [T1], [T2], [F1], [F2], [F3] appearing on the histogram).
Neutropenia* (Neutro-)	Abnormal	Low neutrophil count (NEUT# ≤1.00×10³/µL or NEUT% ≤0.0%).
Neutrophilia* (Neutro+)	Abnormal	High neutrophil count (NEUT# ≥11.00×10³/µL or NEUT% ≥100.0%).
Lymphopenia* (Lympho-)	Abnormal	Low lymphocyte count (LYMPH# ≤0.80×10³/µL or LYMPH% ≤0.0%).
Lymphocytosis* (Lympho+)	Abnormal	High lymphocyte count (LYMPH# ≥4.00×10³/µL or LYMPH% ≥100.0%).
Leukocytopenia* (Leuko-)	Abnormal	Low leukocytes count (WBC ≤2.50×10³/µL).
Leukocytosis* (Leuko+)	Abnormal	High leukocytes count (WBC ≥18.00×10³/µL).
Note: An asterisk (*) indicates the judgment value is user-programmable.		

Annex C: RBC IP Messages (Flags)

IP Message	Type	Meaning
RBC Abn Distribution (RBC Abn Dst)	Abnormal	Abnormal RBC particle size distribution (e.g., due to flags like [RL], [RU], [MP], [DW] appearing on the histogram).
Dimorphic Population (Dimorph Pop)	Abnormal	Double-peak RBC distribution (judged from the histogram shape).
Anisocytosis* (Aniso)	Abnormal	Anisocytosis (RDW−SD ≥65.0 fL or RDW−CV ≥20.0%).
Microcytosis* (Micro)	Abnormal	Microcytosis (MCV ≤70.0 fL).
Macrocytosis* (Macro)	Abnormal	Macrocytosis (MCV ≥110.0 fL).
Hypochromia* (Hypochromia)	Abnormal	Hypochromia (MCHC ≤29.0 g/dL).
Anemia* (Anemia)	Abnormal	Anemia (HGB ≤10 g/dL).
Erythrocytosis* (Erythro+)	Abnormal	Erythrocytosis (RBC ≥6.50×106/µL).
RBC Agglutination? (RBC Agglut?)	Suspect	Possibility of RBC agglutination (judged from RBC distribution and HGB parameters).
Turbidity/HGB Interf? (Turb/HGB?)	Suspect	Effect on haemoglobin by chylæmia (judged from HGB related parameters).
Iron Deficiency? (Iron Def?)	Suspect	Suspected iron deficiency (judged from RBC distribution and HGB parameters).
HGB Defect? (HGB Defect?)	Suspect	Haemoglobin abnormality (judged from RBC distribution related parameters).
Fragments? (Fragments?)	Suspect	Suspected appearance of fragmented red blood cells (judged from RBC and PLT distribution).
Note: An asterisk (*) indicates the judgment value is user-programmable.		

Annex D: PLT IP Messages (Flags)

IP Message	Type	Meaning
PLT Abn Distribution (PLT Abn Dst)	Abnormal	Abnormal PLT particle size distribution (e.g., due to flags like [PL], [PU], [MP], [DW] appearing on the histogram).
Thrombocytopenia* (Thrombo-)	Abnormal	Thrombocytopenia (PLT ≤60×10³/µL).
Thrombocytosis* (Thrombo+)	Abnormal	Thrombocytosis (PLT ≥600×10³/µL).
PLT Clumps/Larger PLT? (PLTC/L-PLT?)	Suspect	Possibility of PLT clumps and larger PLT (e.g., due to the [AG] flag).
Note: An asterisk (*) indicates the judgment value is user-programmable.		

Annex E: Histogram Flag Meanings

These flags directly relate to the DC Impedance Method used for WBC counting and the 3-part differential, which uses electronic discriminators (or boundaries) to separate cell populations based on size.

1. Discriminator Flags (WL, WU, T1, T2)

Flag	Full Name	Location	Meaning
[WL]	**White Lower Discriminator**	The lower boundary of the WBC count.	Indicates that the cell count extends below the WL boundary. This often suggests the presence of very small particles that the instrument counts, such as unlysed RBCs (due to cold agglutinins or lysing failure), severe giant platelets that failed to shrink, or other debris.
[WU]	**White Upper Discriminator**	The upper boundary of the WBC count.	Indicates that the cell count extends above the WU boundary. This usually suggests the presence of WBC clumps or abnormal cells that are significantly larger than normal leukocytes.
[T1]	**Trough Discriminator 1**	Separates the Small Cell (LYMPH) population from the Middle Cell (MXD) population.	Indicates that the analyzer could not find a clear valley (trough) between the Lymphocyte and MXD populations, often due to an abnormal distribution or overlapping cell sizes in this region.
[T2]	**Trough Discriminator 2**	Separates the Middle Cell (MXD) population from the Large Cell (NEUT) population.	Indicates that the analyzer could not find a clear valley (trough) between the MXD and Neutrophil populations, suggesting an abnormal distribution or overlapping cell sizes in the large cell region.

2. Failure Flags (F1, F2, F3)

These codes signal a failure in the counting or measuring process itself:

Flag	Meaning	Implication
[F1]	**Failure 1 (WBC/HGB)**	Indicates a failure in the WBC or HGB measuring channel. This often occurs if the background check fails (i.e., too many particles are present in the diluent or lysing solution), which can signal contamination or an upcoming clog.
[F2]	**Failure 2 (RBC/PLT)**	Indicates a failure in the RBC/PLT measuring channel. This typically signals an issue with the sample or the aperture integrity, often due to a clog in the RBC aperture.
[F3]	**Aperture Clog**	A generic flag that specifically indicates a clog in one of the detector apertures (often the RBC/PLT aperture).

Whenever these flags appear, they typically trigger a corresponding Abnormal Distribution (Abn Dst) IP Message, and the sample requires technician review, troubleshooting (like running the Clog Removal procedure), or a manual blood smear assessment.

Annex E: Sysmex XQ-520 Linearity (Reportable) and Display Ranges

Parameter	Unit	Measuring Interval (Reportable Range)	Display Range
WBC	×103/µL	0.20 to 99.90	0.00 to 999.99
RBC	×106/µL	0.01 to 7.00	0.00 to 99.99
HGB	g/dL	0.1 to 25.0	0.0 to 30.0
HGB	mmol/L	0.1 to 15.6	0.0 to 18.6
HCT	%	0.2 to 60.0	0.0 to 100.0
PLT	×103/µL	5 to 999	0 to 9999
NEUT# (W-LCC)	×103/µL	0.20 to 99.90	0.00 to 999.99
LYMPH# (W-SCC)	×103/µL	0.20 to 99.90	0.00 to 999.99
MXD# (W-MCC)	×103/µL	0.20 to 99.90	0.00 to 999.99
MCV, MCH, MCHC, MPV	Varies	Not Configured*1	Varies
RDW-SD, RDW-CV, PDW, P-LCR, PCT	Varies	Not Configured*2	Varies
NEUT%, LYMPH%, MXD%	%	Not Configured*2	0.0 to 100.0

Display Range: The maximum numerical value the analyzer's software can show.
Measuring Interval (Reportable Range): The range of values where the analyzer has been validated to provide results with guaranteed accuracy and precision (Linearity). **Not Configured*1 Calculation Parameters:** Parameters marked with N/A*1 (MCV, MCH, MCHC, MPV) are calculated from an equation, and thus their measuring interval is not directly configured. **Not Configured*2 Distribution Parameters:** Parameters marked with N/A*2 (RDW-SD, RDW-CV, PDW, P-LCR, PCT, and all differentials in percentage) are calculated from particle size distributions, and thus their measuring interval is not directly configured.