RESEARCH PAPER

Evaluation of Between-Run Precision of Sysmex XN-1000 Automated Hematology Analyser Using Three Levels of Quality Control Material with Short-Term Stability Assessment of Retained EDTA Blood Samples

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ABSTRACT

Automated hematology analyzers are essential for accurate and reliable complete blood count (CBC) analysis. Evaluation of analyzer precision and sample stability is important for laboratory quality assurance.

Aim

To evaluate the between-run precision of the Sysmex XN-1000 automated hematology analyzer and assess short-term stability of retained EDTA blood samples.

Materials and Methods

This analytical observational study was conducted over 2 months using low, normal, and high-level quality control materials. Parameters studied included Hb, RBC count, WBC count, platelet count, and red cell indices. Mean, SD, and coefficient of variation (CV%) were calculated. Retained EDTA samples were reanalyzed after 6–8 hours to assess sample stability.

Results

Hb, RBC, WBC, and red cell indices showed excellent precision with CV% values below 2%. Platelet counts demonstrated comparatively higher variability. Monocytes and basophils showed highest variability among differential counts. Retained EDTA samples remained stable with minimal variation in major CBC parameters.

Conclusion

The Sysmex XN-1000 analyzer demonstrated excellent between-run precision and acceptable short-term stability, confirming its reliability for routine hematology laboratory use.

Keywords: Sysmex XN-1000, Hematology analyzer, Precision, Quality control, CBC, Sample stability.

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INTRODUCTION

Automated hematology analyzers play an essential role in modern diagnostic laboratories by providing rapid, accurate, and reproducible complete blood count (CBC) analysis. Precision and reliability of CBC parameters are important for diagnosis and monitoring of anemia, infections, hematological malignancies, and inflammatory disorders. Between-run precision is an important component of laboratory quality assurance and reflects long-term analyzer stability and reproducibility. According to CLSI guidelines, analytical precision should be evaluated using quality control materials and expressed as coefficient of variation (CV%). [1,2]

Pre-analytical variables such as sample storage may also influence hematological parameters. Prolonged storage of EDTA blood samples can lead to RBC swelling, platelet aggregation, and leukocyte degeneration, thereby affecting analyzer performance. Previous studies have demonstrated that platelet counts and red cell indices are more susceptible to storage-related changes compared with hemoglobin and RBC counts. [3,6]

The Sysmex XN-1000 automated hematology analyzer utilizes fluorescence flow cytometry and impedance-based technologies for precise hematological analysis. The present study was undertaken to evaluate the between-run precision of the Sysmex XN-1000 analyzer using three levels of internal quality control material and to assess the

short-term stability of retained EDTA blood samples over a period of 2 months. [4,7,8]

AIM and OBJECTIVES

The aim of the present study was to evaluate the between-run precision of the Sysmex XN-1000 automated hematology analyzer and to assess the short-term stability of retained EDTA blood samples under routine laboratory conditions. The objectives of the study were to assess between-run precision using three levels of quality control material, calculate mean, standard deviation, and coefficient of variation (CV%), compare the observed precision with standard acceptable limits, and evaluate percentage variation in CBC parameters after 6–8 hours of sample storage.

MATERIALS AND METHODS

This analytical observational study was conducted in the Hematology Laboratory, Department of Pathology, MGM Medical College and Hospital, Navi Mumbai, over a period of 2 months to evaluate the between-run precision of the Sysmex XN-1000 automated hematology analyzer and assess short-term stability of retained EDTA blood samples. Commercially available low, normal, and high-level quality control materials were analyzed daily. Parameters studied included Hb, RBC count, WBC count, platelet count, PCV, MCV, MCH, MCHC, and differential leukocyte counts. Mean, standard deviation (SD), and coefficient of variation (CV%) were calculated using the formula:

CV% = SD/Mean X 100

The observed CV% values were compared with CLSI guidelines and published studies. [1,2,5]

Short-term stability was assessed by reanalyzing retained K2-EDTA blood samples after 6–8 hours of storage and calculating percentage variation between initial and repeat analysis. [3,6]

Inclusion Criteria

- Low, normal, and high QC materials
- Properly collected EDTA samples
- Retained samples available for repeat analysis

Exclusion Criteria

- Clotted or hemolyzed samples
- Inadequate sample volume
- Improperly labeled samples
- Samples with analyzer error flags

Statistical analysis included mean, SD, CV%, and percentage variation

RESULTS

The present analytical observational study was conducted over a period of 2 months to evaluate the between-run precision of the Sysmex XN-1000 automated hematology analyzer using three levels of internal quality control material and to assess short-term stability of retained EDTA blood samples. Parameters evaluated included Hb, RBC count, WBC count, platelet count, red cell indices, and differential leukocyte counts. The findings were compared with published studies and CLSI/ICSH recommendations. [1–6]

Hemoglobin Precision

Hemoglobin demonstrated excellent analytical precision with CV% values below 2% across all QC levels, indicating minimal analytical variability and stable analyzer performance. Similar findings were reported by Seo JY et al. and Buttarello M et al. [3,4]

Table 1. Hemoglobin Precision

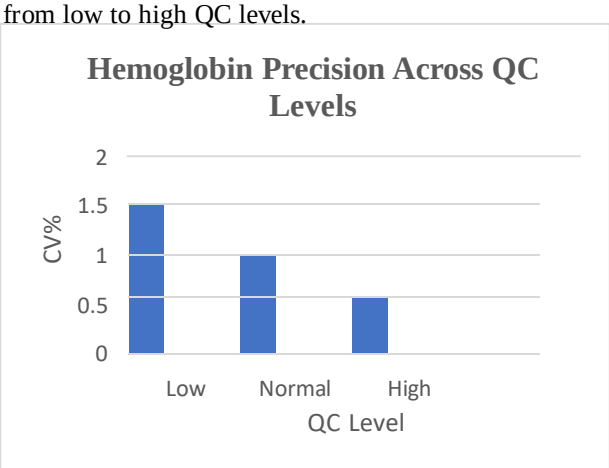
QC Level	Mean	SD	CV%
Low	8.2	0.12	1.52
Normal	13.4	0.12	0.90
High	17.6	0.10	0.57

Observation

- Excellent reproducibility with decreasing CV% at higher QC levels.

Graph 1

Bar graph showing progressive decrease in CV% from low to high QC levels.



RBC Count Precision

RBC counts showed excellent precision with CV% ranging from 0.80% to 1.12%, confirming stable

impedance-based erythrocyte counting. Similar findings were reported by Briggs C et al. [5]

Table 2. RBC Precision

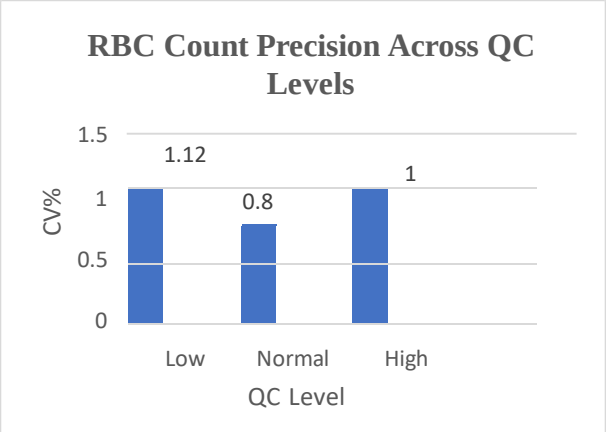
QC Level	Mean (x10^6/uL)	SD	CV%
Low	2.85	0.03	1.12
Normal	4.52	0.04	0.80
High	6.15	0.06	1.00

Observation:

- Minimal day- to-day analytical variation observed.

Graph 2

Bar graph demonstrating uniformly low CV% values for RBC counts across all QC levels.



WBC Count Precision

WBC counts demonstrated excellent analytical precision with CV% values ranging from 1.00% to 1.74%. Stable fluorescence flow cytometry-based leukocyte counting was observed throughout the study period. [4]

Table 3. WBC Precision

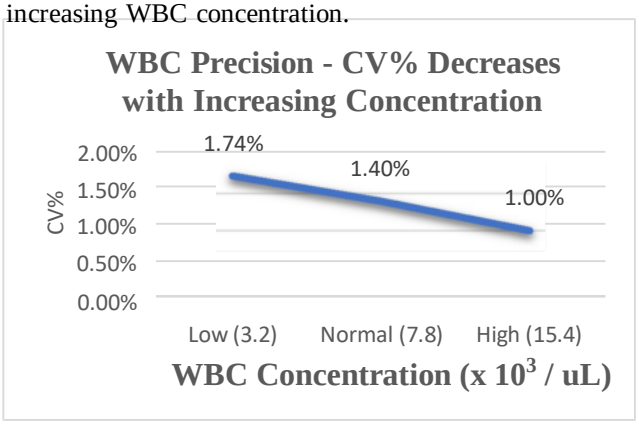
QC Level	Mean	SD	CV%
Low	3.2	0.05	1.74
Normal	7.8	0.11	1.40
High	15.4	0.15	1.00

Observation

- Improved precision observed at higher QC levels

Graph 3

Line graph showing a decrease in CV% with increasing WBC concentration.



Red Cell Indices

MCV, MCH, and MCHC showed excellent analytical stability with CV% values below 2%, correlating with studies by Lippi G et al. [6]

Table 4. Red Cell Indices Precision

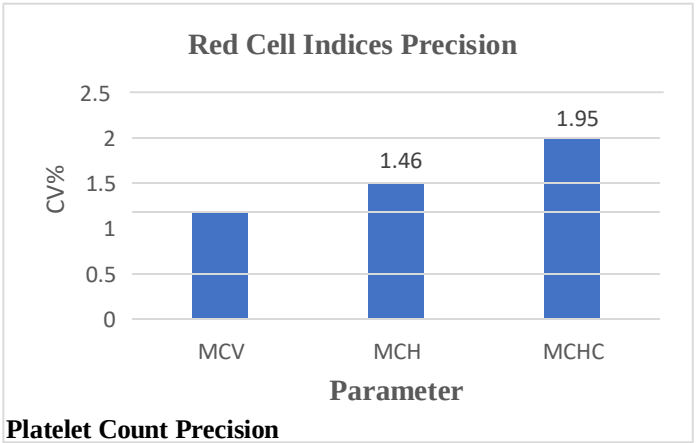
Parameter	Mean	CV%
MCV	88.4	1.18
MCH	29.6	1.46
MCHC	33.5	1.95

Observation

- Excellent precision observed for all red cell indices.

Graph 4

Bar graph comparing CV% of MCV, MCH, and MCHC showing minimal variation.



Platelet Count Precision

Platelet counts showed relatively higher variability, particularly in low-level controls, consistent with

previous studies by Lippi G et al. and Daves M et al. [3,6]

Table 5. Platelet Precision

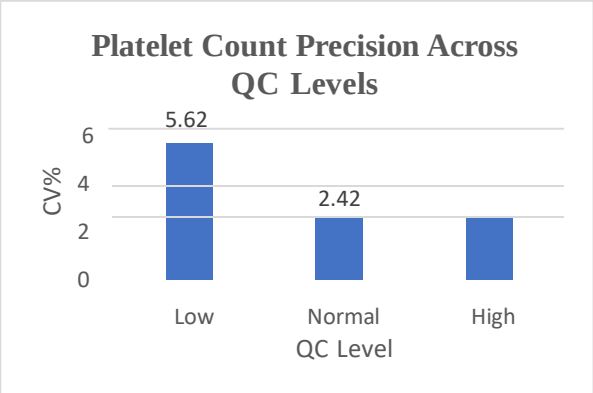
QC Level	Mean	CV%
Low	78	5.62
Normal	242	2.42
High	498	2.68

Observation

- Higher variability noted at lower platelet counts.

Graph 5

Bar graph showing the highest CV% in low-platelet controls.



Differential Leukocyte Counts

Monocytes and basophils showed highest variability due to low absolute counts and gating overlap during automated classification. Similar findings have been reported in ICSH guidelines. [5]

Table 6. Differential Leukocyte Count Variability

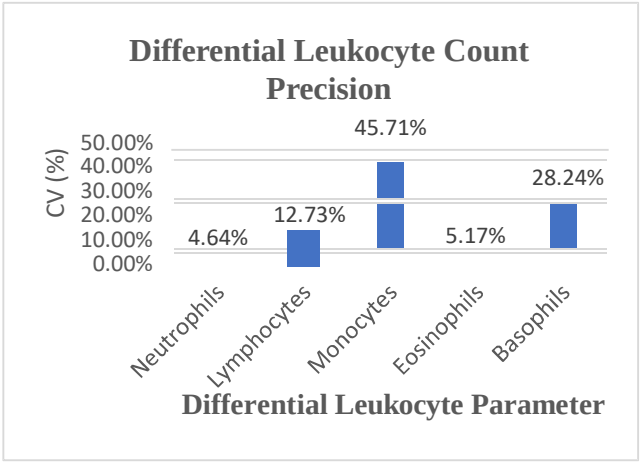
Neutrophils	4.64
Lymphocytes	12.73
Monocytes	45.71
Basophils	28.24

Observation

- Monocytes and basophils demonstrated highest variability.

Graph 6

Column chart demonstrating increased variability in monocytes and basophils.



Short-Term Stability Study

Retained EDTA blood samples remained relatively stable after 6–8 hours. Hb, RBC, and WBC showed minimal variation, while platelet counts demonstrated mild reduction and MCV showed slight increase. Similar findings were reported by Daves M et al. [3]

Table 7. Short-Term Stability

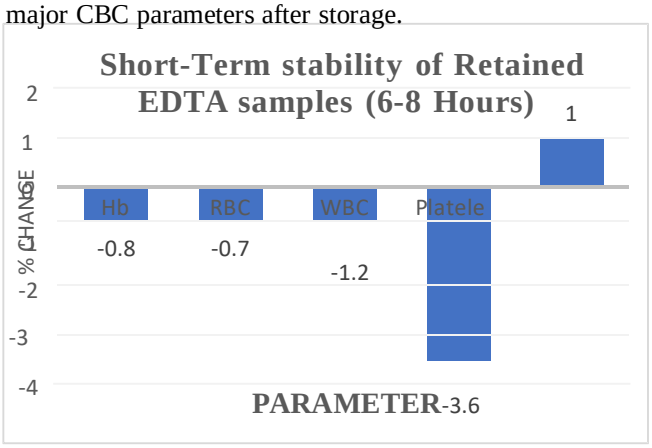
Parameter	% Change
Hb	-0.8
RBC	-0.7
WBC	-1.2
Platelets	-3.6
MCV	+1.0

Observation

- Hb, RBC, and WBC remained stable, while platelets decreased slightly and MCV increased mildly after stortage.

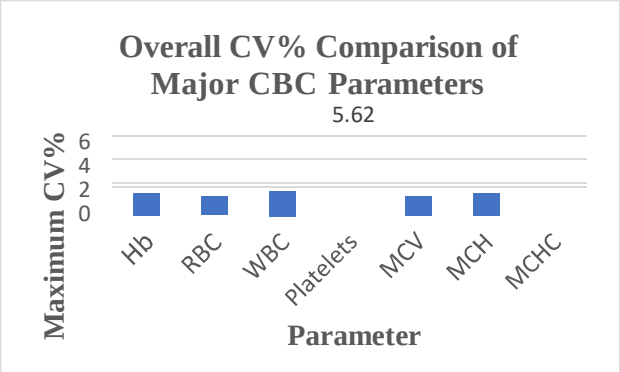
Graph 7

Bar graph showing minimal percentage variation in major CBC parameters after storage.



Graph 8

Overall maximum CV% comparison of major CBC parameters.



DISCUSSION

The present study demonstrated excellent between-run precision of the Sysmex XN-1000 automated hematology analyzer over a 2-month period using three levels of internal quality control material. Major CBC parameters including hemoglobin, RBC count, WBC count, and red cell indices showed low CV% values, indicating stable analyzer performance and good analytical reproducibility. Similar findings have been reported by Seo JY et al. and Briggs C et al. in studies evaluating Sysmex XN-series analyzers. [4,5] Hemoglobin, RBC count, and WBC count demonstrated excellent precision with CV% values below 2%, confirming reliable analyzer performance. The stable analytical performance observed in the present study may be attributed to fluorescence flow cytometry, impedance technology, and automated calibration systems employed in the Sysmex XN-1000 analyzer. Similar observations were reported in previous automated hematology analyzer studies. [4,5]

Red cell indices including MCV, MCH, and MCHC also demonstrated low analytical variability. Stable red cell indices are important for accurate classification of anemia and reliable hematological interpretation. Similar findings were reported by Lippi G et al. in studies evaluating analytical stability of hematological parameters. [6]

Platelet counts showed comparatively higher variability, especially in low-level controls. This may be due to platelet aggregation, platelet satellitism, fragmented RBC interference, and low-count statistical variation. Similar increased platelet variability has been reported by Daves M et al. and Lippi G et al. [3,6]

Differential leukocyte counts demonstrated higher variability in monocytes and basophils, likely due to low absolute cell counts and gating overlap during automated classification. Similar findings have been described in ICSH guidelines and previous analyzer evaluation studies. [5]

The short-term stability study demonstrated that Hb, RBC, and WBC counts remained relatively stable after 6–8 hours of storage in EDTA anticoagulant. Mild increase in MCV and slight reduction in platelet counts were observed after storage, correlating with findings reported by Daves M et al. and Lippi G et al. [3,6]

Comparison with Published Studies

The findings of the present study demonstrate strong agreement with those of previously published studies evaluating automated hematology analysers.

Reference Study	Major Findings	Present Study Correlation
Seo JY et al.	Excellent Hb, RBC, WBC precision	Similar findings
Daves M et al.	MCV rise and platelet decline during storage	Similar observations
Lippi G et al.	Platelet variability greater than Hb/RBC	Similar findings
Briggs C et al.	Basophil and monocyte variability	Similar findings

Overall, the findings of the present study confirm that the Sysmex XN-1000 automated hematology analyzer provides reliable analytical precision and acceptable short-term sample stability, supporting its routine use in high-volume hematology laboratories.

CONCLUSION

The Sysmex XN-1000 automated hematology analyser demonstrated excellent between-run precision for major CBC parameters and acceptable short-term stability in retained EDTA blood samples. The analyser is highly reliable in routine hematology laboratory practice.

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