JPPIPA 12(7) (2026)

Jurnal Penelitian Pendidikan IPA

http://jppipa.unram.ac.id/index.php/jppipa/index

Implementation of Six Sigma as A Quality Control Evaluation of Routine Blood Testing on The Sysmex Xn-1000 Hematology Analyzer

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Received: May 22, 2026
Revised: June 27, 2026
Accepted: July 25, 2026
Published: July 31, 2026

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DOI: 10.29303/jppipa.v12i7.15802

Abstract: This study aimed to evaluate the analytical performance of routine hematology parameters on the Sysmex XN-1000 Hematology Analyzer using the Six Sigma approach. A quantitative descriptive study with an evaluative design was conducted using secondary internal quality control data collected from the Bandung City Regional Health Laboratory during February–March 2025. The analyzed parameters included hemoglobin (HGB), hematocrit (HCT), leukocytes (WBC), platelets (PLT), and erythrocytes (RBC) at three levels of control materials. Precision was assessed using the coefficient of variation (CV), while accuracy and total allowable error (TEa) were used to calculate sigma metrics. Parameters with sigma values below four were further evaluated using the Quality Goal Index (QGI). The results demonstrated that all parameters had acceptable precision, with CV values below 0.33 TEa, and total error values remained within the allowable limits. Hemoglobin and erythrocyte parameters exhibited excellent analytical performance (5–6 sigma), while leukocyte parameters achieved world-class performance (>6 sigma). Hematocrit and platelet parameters showed good performance (4–5 sigma), whereas several parameters with sigma values below four indicated problems related to imprecision, inaccuracy, or both. The findings indicate that the analytical performance of the Sysmex XN-1000 is generally satisfactory and support the implementation of Sigma Matrix-based quality control strategies to improve laboratory efficiency and reliability.

Keywords: Analytical performance; Clinical laboratory; Hematology analyzer; Sysmex XN-1000; Six Sigma; Quality control; Quality Goal Index.

Introduction

Clinical laboratories play a central role in modern healthcare because laboratory test results support disease diagnosis, therapeutic monitoring, prognosis, and clinical decision-making. It has been estimated that approximately 70% of medical decisions rely on laboratory information, highlighting the importance of maintaining reliable analytical performance throughout the testing process (Hicks et al., 2021). Consequently, laboratory quality management has evolved from conventional quality assurance toward risk-based quality systems that prioritize patient safety and continuous performance improvement. The implementation of ISO 15189:2022 further emphasizes that accredited medical laboratories should establish comprehensive internal quality control (IQC), risk management, and continuous monitoring systems to ensure the validity and reliability of examination results (ISO, 2022). Recent recommendations from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) also emphasize that quality indicators and risk-based quality management are fundamental components of patient-centered laboratory medicine because analytical errors may directly

How to Cite:
Wahid, A. A., Kafesa, A., Murtafi'ah, N., & Wahyu, C. (2026). Implementation of Six Sigma as A Quality Control Evaluation of Routine Blood Testing on The Sysmex Xn-1000 Hematology Analyzer. *Jurnal Penelitian Pendidikan IPA*, *12*(7), 663–677. https://doi.org/10.29303/jppipa.v12i7.15802

influence clinical outcomes and patient safety (Giannoli et al., 2025; Sciacovelli et al., 2011).

Internal quality control constitutes the primary mechanism for monitoring analytical performance during routine laboratory operation. Conventional IQC commonly relies on Levey–Jennings charts and Westgard multirules to identify random and systematic analytical errors before patient results are released. Although these approaches are effective for detecting analytical deviations, they provide limited information regarding the overall analytical capability of an examination method relative to predefined quality requirements. Therefore, laboratories have increasingly adopted Six Sigma metrics, which integrate analytical precision, analytical bias, and allowable analytical error into a single performance indicator, allowing quality control procedures to be designed according to analytical risk rather than empirical practice (Westgard et al., 2018). Recent studies have further demonstrated that sigma metrics facilitate optimization of QC frequency, selection of appropriate Westgard multirules, reduction of unnecessary QC events, and improvement of laboratory efficiency while maintaining analytical quality (Badrick & Theodorsson, 2024; Hu et al., 2025).

The Six Sigma methodology combines three principal analytical performance indicators: precision, expressed as the coefficient of variation (CV); accuracy, represented by analytical bias; and Total Allowable Error (TEa). This integrated approach provides a more comprehensive evaluation than conventional IQC because it simultaneously considers random error, systematic error, and clinically acceptable analytical limits. Laboratories achieving higher sigma values generally require fewer quality control procedures, whereas lower sigma values indicate the need for more stringent quality control strategies and corrective actions. Moreover, sigma metrics can be complemented by the Quality Goal Index (QGI) to determine whether reduced analytical performance is primarily attributable to imprecision, inaccuracy, or both, thereby supporting more targeted quality improvement interventions (Çevlik & Haklar, 2024; Westgard et al., 2018). IFCC recommendations also advocate integrating sigma metrics into laboratory risk management because analytical performance directly influences patient risk and the selection of individualized IQC procedures (Giannoli et al., 2025).

One of the most critical factors influencing sigma metric evaluation is the selection of an appropriate Total Allowable Error (TEa) specification. Several TEa sources are currently available, including Biological Variation (BV), Clinical Laboratory Improvement Amendments (CLIA), RiliBÄK, and other regulatory or consensus-based analytical performance specifications. Because these specifications differ considerably in their allowable limits, identical analytical data may yield substantially different sigma values depending on the TEa source applied. Previous studies have consistently demonstrated that sigma performance is highly dependent on the selected TEa specification, highlighting the importance of carefully choosing clinically appropriate quality goals when evaluating laboratory performance (Berta et al., 2023). Furthermore, recent international discussions on analytical performance specifications emphasize that performance goals should be selected according to the intended clinical use, analytical capability, and patient risk rather than applying a single specification universally (Jones et al., 2024). Likewise, (Westgard et al., 2018)recommend adopting a hierarchical approach when selecting analytical performance specifications to avoid underestimating or overestimating laboratory analytical performance and to ensure that quality control strategies remain clinically appropriate.

Several investigators have applied Six Sigma metrics to evaluate automated hematology analyzers and have demonstrated their usefulness for identifying analytical weaknesses and optimizing internal quality control procedures (Berta et al., 2023; Dy et al., 2024). Nevertheless, most published studies have relied on relatively short observation periods, typically one to three months of IQC data. Such evaluations may not adequately reflect routine analytical performance because they are more susceptible to temporary fluctuations caused by reagent lot replacement, calibration adjustment, preventive maintenance, environmental variation, and instrument drift. Consequently, sigma values derived from short-term datasets may not accurately represent long-term analytical capability (Sciacovelli et al., 2011; Westgard et al., 2018). Recent IFCC guidance further recommends continuous monitoring of laboratory quality indicators to better characterize analytical performance and support sustainable quality improvement in accredited laboratories (Sciacovelli et al., 2011).

To date, studies evaluating hematology analytical performance using a long-term average of IQC precision combined with hierarchical TEa selection remain limited, particularly for automated hematology analyzers used in routine clinical laboratories. Most previous investigations calculated sigma metrics using a single TEa source and relatively short monitoring periods, which may not fully represent routine analytical performance. Therefore, the present study evaluated the analytical performance of the Sysmex XN-1000 hematology analyzer by combining a six-month average coefficient of variation (CV) with monthly analytical bias and applying a hierarchical TEa selection algorithm. This approach was expected to provide a more representative assessment of long-term analytical

capability, identify the most appropriate TEa specification for each hematological parameter, and support the development of individualized, risk-based internal quality control strategies in accordance with current international recommendations.

Method

This study employed a quantitative descriptive design with an evaluative approach utilizing the Six Sigma method. The study was conducted at the Bandung City Regional Health Laboratory using secondary data from the Internal Quality Improvement (PMI) for the February–March 2025 period.

Research Population

The study population was all control material examination data on the Sysmex XN-1000 Hematology Analyzer. The study sample consisted of three levels of quality control data (low, normal, and high) for hemoglobin (HGB), hematocrit (HCT), leukocytes (WBC), platelets (PLT), and erythrocytes (RBC).

Research Stages Include:

1. Collection of data from the results of the control material examination.
2. Calculation of mean and standard deviation.
3. Coefficient of Variation (CV) calculation:

$$CV(\%) = \frac{SD}{Mean} x\ 100 \quad (1)$$

where:
SD = standard deviation
Mean = average IQC value

4. Bias (%) Calculation:

$$Bias\ (\%) = \frac{Laboratory\ Mean - Target\ Mean}{Target\ Mean}\ x\ 100 \quad (2)$$

where:
Laboratory Mean = laboratory mean IQC value
Target Mean = manufacturer/peer group mean

5. Determination of Total Error Allowable (TEa) based on the appropriate TEa source.

$$TE\ (\%) = Bias\ (\%) + 1.65 \times CV\ (\%) \quad (3)$$

6. The Sigma value is calculated using the following formula:

$$Sigma = \frac{TE_{\alpha} - Bias}{CV} \quad (4)$$

where:
TEa = Total Allowable Error (CLIA)
Bias = systematic error
CV = coefficient of variation

7. Evaluasi parameter dengan nilai sigma <4 menggunakan Quality Goal Index (QGI).

$$QGI = \frac{Bias}{1.5\ x\ CV} \quad (5)$$

Interpretation:

- QGI < 0.8 → imprecision problem
- QGI 0.8–1.2 → both imprecision and inaccuracy
- QGI > 1.2 → inaccuracy problem

Six Sigma analysis was performed using internal quality control (IQC) data. Precision was assessed by calculating the coefficient of variation (CV), while accuracy was evaluated using bias relative to the target mean. Total analytical error (TE) was calculated by combining systematic and random errors. Sigma metrics were then determined using the CLIA Total Allowable Error (TEa) values. For parameters with sigma values below six, the Quality Goal Index (QGI) was calculated to identify whether analytical performance was predominantly affected by imprecision, inaccuracy, or both. Based on the obtained sigma values, appropriate Westgard quality control rules were selected to optimize internal quality control procedures.

Data analysis

The data was analyzed descriptively and presented in the form of tables and interpretation of the sigma performance level.

Result and Discussion

The value source mapping results

This study was conducted at the Bandung City Regional Health Laboratory, Indonesia, using secondary Internal Quality Control (IQC) data collected from February to March 2025. Hematology analyses were performed using the Sysmex XN-1000 hematology analyzer with three levels of commercial control materials. The selection of Total Allowable Error (TEa) followed the hierarchical Westgard TEa selection algorithm, in which each hematology parameter was initially evaluated using Desirable Biological Variation (BV). Analytical performance was subsequently classified into four decision areas (A–D), where Area A indicates that the selected TEa appropriately represents analytical performance, whereas Areas B–D require reevaluation using alternative TEa specifications (Figures 1–3).

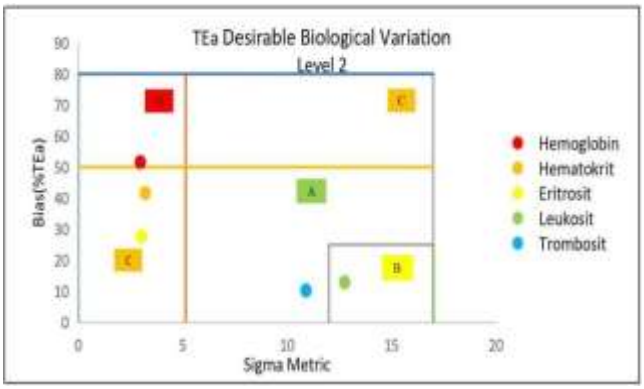

Figure 1. Performance test mapping graph using TEa Desirable Biological Variation Control Level 2.

At control levels 1 and 2, platelet was classified in Area A, indicating that the Desirable Biological Variation (BV)-based analytical performance specification appropriately reflected its analytical performance. In contrast, leukocyte was initially classified in Area B, suggesting that the selected Total Allowable Error (TEa) specification may have been overly permissive relative to the observed analytical capability and therefore required reassessment using the more stringent Optimal BV criterion. Hemoglobin, hematocrit, and erythrocytes were predominantly distributed in Areas C and D, indicating a mismatch between their analytical performance and the selected TEa specification. Similar results were observed at control level 3, where only platelet and leukocyte satisfied the acceptance criteria. These findings highlight the importance of verifying the suitability of analytical performance specifications because inappropriate TEa selection may either overestimate or underestimate method performance, ultimately affecting sigma metric interpretation and quality control design (Aarsand et al., 2018; Badrick & Theodorsson, 2024).

Following the Westgard TEa selection algorithm, leukocyte was subsequently re-evaluated using Optimal Biological Variation, resulting in its reclassification into Area A, indicating that a more stringent biological variation–based specification provided a better representation of its analytical capability. Parameters classified in Areas C and D were then reassessed using Minimum Biological Variation, consistent with the hierarchical application of biological variation–derived analytical performance specifications. This recalculation improved the analytical classification of hematocrit and erythrocytes at control levels 1 and 2, whereas hemoglobin remained outside the acceptable analytical region. Likewise, at control level 3, hemoglobin, hematocrit, and erythrocytes continued to fall outside Area A, suggesting that their analytical performance did not satisfy even the minimum biological variation–based performance specification. These observations indicate that the appropriateness of TEa selection is a critical determinant of sigma metric interpretation and emphasize that biological variation–based analytical performance specifications should be carefully selected according to analyte characteristics and intended clinical application (Aarsand et al., 2018; Panteghini & Sandberg, 2015).

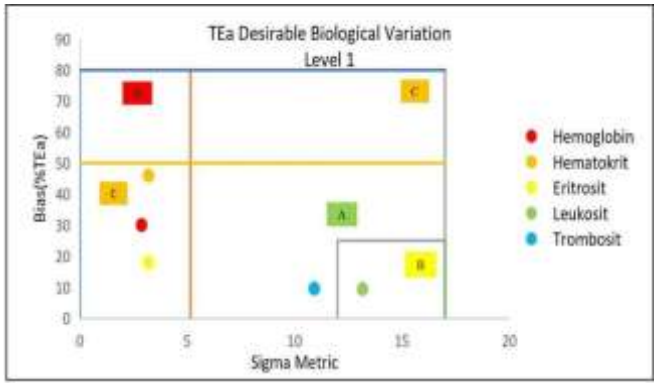

Figure 2. Performance test mapping graph using TEa Desirable BiologicalVariation control level 1.

Additional evaluation using alternative TEa specifications demonstrated that the RiliBÄK quality specification did not substantially improve the analytical classification of hemoglobin and hematocrit. Conversely, recalculation using CLIA-derived TEa shifted all hemoglobin and hematocrit measurements to Area A, indicating that CLIA quality specifications were more suitable than Biological Variation-derived TEa for evaluating these parameters in the present laboratory.

The present findings demonstrate that the suitability of analytical performance specifications differed among hematological parameters. Platelet consistently satisfied analytical quality requirements using Desirable Biological Variation (BV)-derived specifications, whereas leukocyte required Optimal BV, erythrocytes required Minimum BV, and hemoglobin and hematocrit were more appropriately evaluated using CLIA-derived Total Allowable Error (TEa) specifications. These observations indicate that no single analytical performance specification is universally applicable to all hematological analytes and support the hierarchical application of analytical performance specifications according to analyte characteristics, biological variation, and clinical purpose, as recommended by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) hierarchy for analytical performance specifications (Aarsand et al., 2018; Panteghini & Sandberg, 2015).

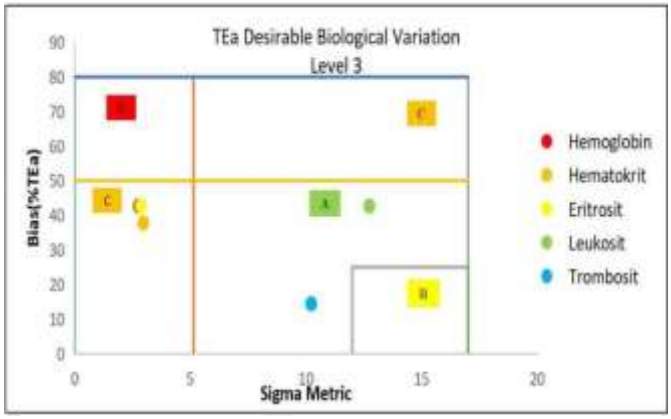

Figure 3. Performance test mapping graph using TEa Desirable Biological Variation Control Level 3.

The consistently acceptable analytical performance observed for platelet is likely attributable to the high analytical precision of the Sysmex XN-1000. Modern hematology analyzers combine impedance and fluorescence flow cytometry with advanced particle discrimination algorithms to improve platelet identification and reduce analytical variability, thereby enhancing measurement repeatability. Consequently, platelet counts frequently demonstrate lower coefficients of variation and superior analytical performance compared with more biologically variable hematological parameters. Similar findings were reported by Li et al. (2023), who observed that platelet measurements exhibited consistently high sigma performance across multiple hematology analyzers, reflecting robust analytical precision and stable measurement performance. These findings are also consistent with analytical performance evaluations showing that platelet parameters generally meet biological variation–based quality specifications more readily than erythrocyte-related parameters, although performance remains dependent on analyzer characteristics, calibration procedures, and the analytical performance specifications applied (Berta et al., 2023; Li et al., 2023).

In contrast, hemoglobin and hematocrit failed to satisfy Biological Variation-derived TEa despite sequential recalculation using progressively less stringent Biological Variation specifications. This finding suggests that Biological Variation-derived quality goals may be excessively stringent for these analytes in routine hematology practice. Similar conclusions were reported by (Badrick & Theodorsson, 2024), who emphasized that sigma performance is highly dependent on TEa selection and that excessively restrictive analytical performance specifications may underestimate actual laboratory capability. Likewise, (Giannoli et al., 2025) recommended selecting analytical performance specifications according to patient risk and intended clinical application rather than relying on a single universal TEa source.

However, the present findings differ from those reported by (Li et al., 2023), who observed sigma values exceeding six for hemoglobin using Biological Variation-derived TEa. The discrepancy may be explained by differences in analytical platforms, calibration traceability, reagent manufacturers, internal quality control materials, monitoring duration, environmental conditions, and laboratory workflow. Sigma metrics are mathematically influenced by both analytical imprecision (CV) and systematic error (bias); therefore, laboratories exhibiting lower CV and bias will naturally achieve higher sigma performance even when identical TEa specifications are applied.

The improvement observed after adopting CLIA-derived TEa indicates that CLIA quality goals more accurately reflect the routine analytical capability of the Sysmex XN-1000 for hemoglobin and hematocrit measurements. Unlike Biological Variation specifications, which are derived from physiological variation among healthy individuals, CLIA establishes allowable analytical error according to clinically acceptable decision limits. Consequently, CLIA-derived TEa often provides a more realistic estimate of routine analytical performance for parameters routinely used in clinical decision-making. Similar conclusions have been reported by (Westgard et al., 2018), who demonstrated that risk-based quality control strategies become more reliable when TEa reflects actual clinical requirements rather than solely biological variation.

From an operational perspective, these findings indicate that platelet and leukocyte require only routine multirule quality control because of their satisfactory analytical performance. In contrast, hemoglobin and hematocrit require closer monitoring of calibration status, reagent stability, preventive maintenance, and quality control frequency. Appropriate TEa selection is therefore critical because it directly influences sigma metrics, Quality Goal Index (QGI), Westgard rule selection, and ultimately the reliability of patient test results. Incorrect TEa selection may either underestimate analytical performance, leading to unnecessarily stringent quality control, or overestimate performance, thereby increasing the risk of clinically significant analytical errors. Therefore, hierarchical TEa selection should be considered an essential component of risk-based laboratory quality management in accordance with ISO 15189:2022 and current IFCC recommendations (Giannoli et al., 2025; Sciacovelli et al., 2011).

TEa value source mapping results

The analytical performance of each hematology parameter was initially evaluated using Total Allowable

Error (TEa) values derived from Desirable Biological Variation (Desirable BV). The use of biological variation–based analytical performance specifications provides clinically relevant quality goals because these specifications reflect the inherent physiological variability of the measurand and facilitate harmonization of laboratory quality assessment (Aarsand et al., 2018). Sigma values obtained from the three internal quality control levels demonstrated that several parameters exhibited different analytical classifications across control concentrations. Such variation is expected because analytical imprecision and systematic bias are influenced by analyte concentration and measurement characteristics, resulting in different analytical capabilities throughout the reportable measurement range (Braga et al., 2023; Jones et al., 2024). Consequently, quality control planning should consider analytical performance at clinically relevant concentrations. Consistent with risk-based statistical quality control principles, the sigma value selected for quality control design should correspond to the quality control level nearest the relevant clinical decision point to ensure that quality control procedures reflect clinically meaningful analytical performance (Westgard et al., 2018).

Table 1 summarizes the hierarchical TEa selection process. Evaluation began using Desirable Biological Variation, followed by Optimal Biological Variation for parameters located in Area B, Minimum Biological Variation for parameters in Areas C and D, and finally alternative TEa specifications (RiliBÄK and CLIA) when acceptable analytical performance could not be achieved. The mapping results demonstrated that platelet, leukocyte, and erythrocyte analyses could be adequately evaluated using Biological Variation-derived TEa, although leukocytes required Optimal BV and erythrocytes required Minimum BV before achieving acceptable analytical performance. In contrast, hemoglobin and hematocrit consistently failed to satisfy all Biological Variation criteria and RiliBÄK specifications, reaching acceptable performance only after recalculation using CLIA-derived TEa.

Table 1. Location of parameters in the area of the graph based on the results of performance evaluation using different TEa sources.

Parameter	Level Kontrol	Des BV	Opt BV	Min BV	RiliBAK	CLIA
Hemoglobin	Level 1	Area C	Area C	Area C	Area C	Area A
Hematokrit	Level 1	Area C	Area C	Area C	Area C	Area A
Leukosit	Level 3	Area B	Area A			
Trombosit	Level 3	Area A				
Eritrosit	Level 3	Area C	Area C	Area A		

These findings indicate that the appropriateness of TEa specifications depends on the analytical characteristics of individual hematology parameters. Biological Variation-derived TEa appears sufficiently applicable for platelet and leukocyte measurements but is excessively stringent for hemoglobin and hematocrit under routine laboratory conditions. Similar observations were reported by (Hu et al., 2025), who showed that sigma values varied substantially according to the TEa source employed and recommended hierarchical TEa selection to avoid misclassification of analytical performance. Likewise, (Westgard et al., 2018)emphasized that inappropriate TEa selection may either underestimate or overestimate sigma metrics, resulting in inefficient quality control strategies.

Comparable findings were also reported by (Li et al., 2023), who found that platelet and erythrocyte parameters generally fulfilled Biological Variation specifications, whereas hemoglobin frequently required less restrictive TEa values because of its inherently narrow allowable biological variation. More recently, Sciacovelli et al., (2011) emphasized that harmonization of analytical performance specifications should consider both biological variation and clinical requirements, since excessive reliance on biological variation alone may produce unrealistically stringent quality targets for several routine hematology analytes.

Conversely, the present findings differ from those reported by (Li et al., 2023), who observed sigma values exceeding six for hemoglobin using Biological Variation-derived TEa. These discrepancies are likely attributable to differences in analyzer platforms, calibration traceability, reagent lots, quality control materials, duration of IQC observation, and laboratory environmental conditions. In the present study, sigma values were calculated using a six-month average IQC dataset, which is more likely to capture long-term analytical variability arising from calibration shifts, preventive maintenance, reagent replacement, and cumulative instrument drift than evaluations based on one- to three-month datasets.

Technically, the inability of hemoglobin and hematocrit to satisfy Biological Variation-derived analytical performance specifications may reflect the relatively stringent allowable analytical error established for these measurands. Because sigma metrics are derived from the relationship among analytical bias, imprecision, and the selected analytical performance

specification, even small increases in either systematic or random error may substantially decrease sigma values when narrow quality specifications are applied. Moreover, the selection of analytical performance specifications should consider the intended clinical application and the analytical characteristics of individual measurands rather than relying on a universal quality goal (Jones et al., 2024; Sandberg et al., 2024). Conversely, platelet measurements demonstrated consistently superior analytical performance, reflecting the lower analytical variability achieved by modern automated hematology analyzers during routine platelet enumeration.

From an operational perspective, these findings indicate that applying a single source of Total Allowable Error (TEa) to all hematology parameters may not provide the most appropriate evaluation of analytical capability. Instead, analytical performance specifications should be selected according to analyte characteristics, biological variation, and clinical purpose, thereby providing a more clinically relevant assessment of method performance. Such an approach supports risk-based laboratory quality management by facilitating appropriate quality control design, efficient allocation of quality control resources, and maintenance of analytical reliability in support of patient safety and clinical decision-making (Jones et al., 2024; Sandberg et al., 2024).

Hematology Examination Precision with 6-Month Control Average

Analytical precision was evaluated using the coefficient of variation (CV%) for hemoglobin, hematocrit, leukocyte, platelet, and erythrocyte measurements at three levels of internal quality control materials. Precision reflects the reproducibility of repeated measurements under identical analytical conditions and represents the random error component incorporated into Six Sigma metrics. According to the Westgard Sigma verification approach, analytical precision is considered acceptable when the coefficient of variation is less than one-third of the selected Total Allowable Error (CV < 0.33 TEa), indicating that random analytical error contributes minimally to total analytical uncertainty (Westgard et al., 2018).

As shown in Table 2, all hematological parameters fulfilled the predefined precision acceptance criterion across all three control levels. Hemoglobin exhibited the lowest CV (0.87%) at control level 3, whereas platelet demonstrated the highest CV (2.98%) at control level 2. Nevertheless, all CV values remained substantially below the corresponding 0.33 TEa threshold, indicating excellent analytical reproducibility and stable performance of the Sysmex XN-1000 during the six-month observation period.

Table 2. Precision Test Results

Parameter	Control material	Nilai CV (%)	TEa	0.33 Tea	Interpretasi	Keputusan
Hemoglobin	Level 1	1,24	7	2,3	1,24 < 2,3	CV received
	Level 2	1,23	7	2,3	1,23 < 2,3	CV received
	Level 3	0,87	7	2,3	0,87 < 2,3	CV received
Hematokrit	Level 1	1,56	6	2,0	1,56 < 2,0	CV received
	Level 2	1,62	6	2,0	1,62 < 2,0	CV received
	Level 3	1,17	6	2,0	1,17 < 2,0	CV received
Leukosit	Level 1	2,15	6,9	2,3	2,15 < 2,3	CV received
	Level 2	1,75	6,9	2,3	1,75 < 2,3	CV received
	Level 3	1,08	6,9	2,3	1,52 < 2,3	CV received
Trombosit	Level 1	2,78	11,3	3,7	2,78 < 3,7	CV received
	Level 2	2,98	11,3	3,7	2,98 < 3,7	CV received
	Level 3	1,52	11,3	3,7	1,52 < 3,7	CV received
Eritrosit	Level 1	1,22	5,8	1,9	1,22 < 1,9	CV received
	Level 2	1,40	5,8	1,9	1,40 < 1,9	CV received
	Level 3	0,94	5,8	1,9	0,94 < 1,9	CV received

The consistently low CV values demonstrate that random analytical error was effectively controlled throughout routine laboratory operation. Since the sigma metric is inversely proportional to analytical imprecision, maintaining a low CV is essential for achieving high sigma performance and reducing unnecessary quality control rejections (Koshy & Raza, 2022). This finding also indicates that the analytical system remained stable despite routine variations associated with daily operation, reagent use, calibration, and preventive maintenance.

Among all parameters, hemoglobin showed the best precision. This result is consistent with the analytical principle of the Sysmex XN-1000, which measures hemoglobin using sodium lauryl sulfate (SLS)-hemoglobin photometry. The SLS method provides excellent analytical stability, minimizes interference from lipemia and leukocytosis, and offers better

reproducibility than the conventional cyanmethemoglobin method (Leite et al., 2022). Consequently, hemoglobin measurements generally exhibit lower analytical variation than cell-counting parameters.

Platelet measurements showed relatively higher CV values than the other hematological parameters, although they remained well within the acceptable analytical limit. Platelet enumeration is analytically more challenging because impedance-based counting is influenced by platelet aggregation, fragmented erythrocytes, microcytosis, giant platelets, coincidence events, and specimen storage. These factors increase analytical variability even when instrument performance remains satisfactory.

The present findings agree with those reported by (Li et al., 2023), who evaluated hematology analyzers using sigma metrics and observed that hemoglobin consistently achieved the lowest analytical imprecision, whereas platelet and leukocyte measurements exhibited relatively higher CV values because of the complexity of cellular counting techniques. Likewise, (Goswami et al., 2025) demonstrated that most routine hematology parameters showed CV values below 3%, indicating that contemporary automated hematology analyzers possess sufficient analytical precision for Six Sigma implementation. (Giannoli et al., 2025)further emphasized that maintaining stable analytical precision is a fundamental requirement for compliance with ISO 15189:2022 because reproducible analytical performance directly improves the reliability and comparability of patient results.

However, the present findings differ from those reported by (Li et al., 2023), who observed greater analytical imprecision for leukocyte and platelet measurements, leading to only marginal sigma performance in several laboratories. Such discrepancies are likely attributable to differences in analyzer configuration, calibration protocols, reagent lots, maintenance schedules, laboratory workload, and environmental conditions. Sciacovelli et al., (2011) also highlighted that inadequate preventive maintenance, reagent instability, and increased analytical workload may adversely affect long-term analytical precision, particularly for cell-counting parameters.

An important strength of the present study is the use of a six-month average of internal quality control data. Compared with studies based on shorter observation periods, long-term monitoring minimizes the influence of temporary analytical fluctuations associated with reagent replacement, calibration adjustment, preventive maintenance, or occasional analytical drift. Consequently, the calculated CV values more accurately represent the routine analytical capability of the Sysmex XN-1000 under real laboratory operating conditions. This approach is consistent with recent recommendations advocating continuous long-term internal quality monitoring as part of risk-based quality management under ISO 15189:2022 (Giannoli et al., 2025).

From a clinical perspective, excellent analytical precision is essential because random analytical variation directly influences the interpretation of serial laboratory results. Small analytical fluctuations in hemoglobin, hematocrit, leukocyte, or platelet measurements may affect anemia diagnosis, transfusion decisions, chemotherapy monitoring, infection assessment, and the evaluation of hematological disorders. Therefore, the consistently acceptable CV values obtained in this study indicate that the Sysmex XN-1000 provides reliable analytical precision for routine hematology testing and establishes a robust foundation for subsequent sigma metric calculation, Quality Goal Index (QGI) analysis, and optimization of risk-based quality control strategies.

Total Error in Hematology Examination using 6 Month Control Average

Total Error (TE) represents the combined contribution of random error (imprecision) and systematic error (bias), thereby providing an integrated measure of analytical performance. Within the Six Sigma framework, analytical performance is considered acceptable when the calculated TE remains below the selected Total Allowable Error (TEa), indicating that both precision and accuracy satisfy predefined quality specifications (Hens et al., 2014).

Table 3. Results of Total Error Measurement for February – March 2025

K	Control material	Total Error (TE %)		Tea	Conclusion
		February	March		
Hemoglobin	Level 1	2,9	1,9	7	TE received
	Level 2	2,4	1,9	7	TE received
	Level 3	1,6	1,4	7	TE received
Hematokrit	Level 1	2,4	1,6	6	TE received
	Level 2	3,0	2,0	6	TE received
	Level 3	4,4	2,4	6	TE received
Leukosit	Level 1	3,2	2,3	6,9	TE received
	Level 2	2,1	3,7	6,9	TE received

K	Control material	Total Error (TE %)		Tea	Conclusion
		February	March		
	Level 3	1,8	1,2	6,9	TE received
Trombosit	Level 1	3,0	4,4	11,3	TE received
	Level 2	5,9	6,4	11,3	TE received
	Level 3	5,9	4,5	11,3	TE received
Eritrosit	Level 1	3,7	4,9	5,8	TE received
	Level 2	2,9	4,4	5,8	TE received
	Level 3	3,2	4,4	5,8	TE received

As presented in **Table 3**, all hematology parameters at control Levels 1–3 during February and March produced TE values below their respective TEa limits. None of the evaluated parameters exceeded the allowable analytical error, demonstrating that the Sysmex XN-1000 consistently maintained acceptable analytical performance throughout the evaluation period. Although platelet and erythrocyte measurements exhibited relatively higher TE values than hemoglobin, their analytical errors remained within acceptable quality specifications.

The consistently acceptable TE values indicate that both random and systematic analytical errors were effectively controlled during routine laboratory operation. Since TE incorporates analytical imprecision (CV) and bias into a single quality indicator, low TE values reflect stable calibration, adequate instrument precision, and minimal systematic deviation from assigned target values. Consequently, the analytical system was capable of producing reliable hematology results suitable for routine clinical application (Westgard et al., 2018).

Among the evaluated parameters, hemoglobin consistently exhibited the lowest TE values, whereas platelet and erythrocyte measurements showed relatively higher values. This finding is consistent with the analytical characteristics of automated hematology analyzers. Hemoglobin is determined using spectrophotometric SLS-hemoglobin technology, which is inherently less susceptible to analytical interference than impedance-based cellular counting. In contrast, platelet and erythrocyte measurements are more vulnerable to variations caused by platelet aggregation, microcytosis, fragmented erythrocytes, coincidence counting, reagent performance, and sample stability, thereby increasing both random and systematic analytical error (Leite et al., 2022).

The present findings are consistent with those reported by Li et al. (2023), who evaluated automated hematology analyzers using sigma metrics and demonstrated that hematology parameters with TE values below the selected TEa consistently achieved acceptable analytical performance. Likewise, (Giannoli et al., 2025) emphasized that maintaining analytical error below predefined quality specifications is an essential component of the ISO 15189:2022 quality management system because it ensures reliable patient results and supports continuous quality improvement. Similar observations were reported by (Goswami et al., 2025), who demonstrated that hematology parameters with Total Error values remaining within the selected analytical performance specifications consistently achieved acceptable sigma performance, thereby reducing the need for frequent quality control investigations and corrective actions.

In contrast, several studies have reported higher TE values for hematology parameters. Li et al., (2023) observed that platelet and erythrocyte measurements occasionally exceeded allowable analytical error because of increased analytical bias associated with calibration drift and reagent lot variation. Similarly, Sciacovelli et al., (2011) reported that laboratories with inadequate preventive maintenance and inconsistent quality management experienced progressive increases in total analytical error, particularly for cellular parameters that are highly sensitive to instrument performance. These discrepancies likely reflect differences in analyzer technology, calibration frequency, quality-control materials, reagent stability, laboratory workload, and environmental conditions.

An important methodological strength of the present study is the use of a six-month internal quality control average for calculating analytical performance. Compared with evaluations based on shorter observation periods, long-term monitoring reduces the influence of temporary fluctuations resulting from reagent replacement, calibration adjustment, preventive maintenance, or day-to-day operational variability. Consequently, the TE values obtained more accurately represent the long-term analytical capability of the Sysmex XN-1000 under routine laboratory conditions. Continuous monitoring over extended periods has also been recommended by Giannoli et al., (2025) as part of risk-based quality management to ensure sustained compliance with ISO 15189:2022 requirements.

From an operational perspective, the acceptable TE values indicate that routine quality management practices—including instrument calibration, preventive maintenance, internal quality control monitoring, and adherence to standard operating procedures—were

effective in minimizing analytical error. This level of analytical performance supports the subsequent application of sigma metrics, Quality Goal Index (QGI), and individualized Westgard multirule selection without requiring major corrective interventions.

From a clinical perspective, maintaining TE below TEa is essential because excessive analytical error may lead to erroneous classification of anemia, polycythemia, thrombocytopenia, leukocytosis, and other hematological disorders. Such analytical inaccuracies may subsequently influence transfusion decisions, infection monitoring, chemotherapy evaluation, and overall patient management. Therefore, the consistently acceptable TE values observed in this study indicate that the Sysmex XN-1000 provides reliable analytical performance capable of supporting accurate clinical decision-making while meeting current laboratory quality requirements.

Sigma Metric of Hematology Examination Based on the Six-Month Control Average

The sigma metric was calculated using the six-month average coefficient of variation (CV) combined with monthly bias values obtained in February and March 2025. This approach provides a more representative estimate of long-term analytical performance because the average CV reflects routine analytical precision over an extended period, whereas monthly bias captures short-term systematic error. Integrating these two indicators allows sigma metrics to better describe analyzer performance under routine laboratory conditions than calculations based on short-term quality control data alone (Sciacovelli et al., 2011; Westgard et al., 2018).

As presented in Tables 4 and 5, sigma values ranged from 3.0 to 7.8, indicating different levels of analytical capability among hematology parameters. Hemoglobin consistently achieved the highest sigma performance, reaching 7.7–7.8 sigma at Control Level 3, corresponding to world-class analytical quality. Leukocyte and platelet measurements also reached the world-class category at Level 3, whereas hematocrit and erythrocyte parameters generally remained within the good (4–6 sigma) or marginal (3–4 sigma) categories.

Table 4. Sigma Measurement Results for February

Parameter	Control material	Nilai CV (%)	Bias (d%)	TE	Sumber Tea	Tea	Sigma	Conclusion
Hemoglobin	Level 1	1,24	0,85	2,93	CLIA	7	5,0	Excelent
	Level 2	1,23	0,61	2,44	CLIA	7	5,2	Excelent
	Level 3	0,87	0,34	1,56	CLIA	7	7,7	World Class
Hematokrit	Level 1	1,27	0,55	2,38	CLIA	6	4,3	Good
	Level 2	1,33	0,82	2,97	CLIA	6	3,9	Marginal
	Level 3	1,17	1,60	4,38	CLIA	6	3,8	Marginal
Leukosit	Level 1	2,15	0,52	3,20	Opt BV	6,9	3,0	Marginal
	Level 2	1,75	0,19	2,13	Opt BV	6,9	3,8	Marginal
	Level 3	1,08	0,38	1,84	Opt BV	6,9	6,0	World Class
Trombosit	Level 1	2,78	0,09	2,96	Des BV	11,3	4,0	Good
	Level 2	2,98	1,45	5,88	Des BV	11,3	3,3	Marginal
	Level 3	1,52	2,18	5,88	Des BV	11,3	6,0	World Class
Eritrosit	Level 1	1,22	1,26	3,74	Min BV	5,8	3,7	Marginal
	Level 2	1,40	0,76	2,92	Min BV	5,8	3,6	Marginal
	Level 3	0,94	1,10	3,14	Min BV	5,8	5,0	Excelent

The excellent sigma performance of hemoglobin is primarily attributable to its combination of **very low analytical imprecision (CV <1%)** and minimal bias. Because sigma metrics are inversely proportional to analytical imprecision, even modest reductions in CV substantially increase sigma values when bias remains stable (Westgard & Westgard, 2023). In addition, the Sysmex XN-1000 measures hemoglobin using the sodium lauryl sulfate (SLS)-hemoglobin photometric method, which has been recommended by the International Council for Standardization in Haematology (ICSH) because of its high analytical stability, good linearity, and reduced interference compared with conventional cyanmethemoglobin methods (Leite et al., 2022). Consequently, hemoglobin measurements generally demonstrate superior analytical reproducibility compared with cell-counting parameters.

In contrast, hematocrit and erythrocyte measurements produced lower sigma values despite acceptable precision. Hematocrit is a calculated parameter that depends on erythrocyte count and mean corpuscular volume (MCV), making it more susceptible to cumulative analytical variation than directly measured parameters. Likewise, erythrocyte enumeration may be influenced by abnormal erythrocyte morphology, sample aging, coincidence events, and pre-analytical factors, all of which may

increase analytical variability and reduce sigma performance (ICSH, 2023). Similar observations have been reported by Li et al., (2023), who found that erythrocyte- and hematocrit-related parameters frequently achieved lower sigma metrics than hemoglobin because small increases in analytical bias markedly reduced sigma values despite acceptable precision.

Table 5. Sigma Measurement Results for March

Parameter	Control material	Nilai CV (%)	Bias (d%)	TE	Source Tea	Tea	Sigma	Conclusion
Hemoglobin	Level 1	1,24	0,34	1,91	CLIA	7	5,4	Excelent
	Level 2	1,23	0,31	1,85	CLIA	7	5,4	Excelent
	Level 3	0,87	0,25	1,37	CLIA	7	7,8	World Class
Hematokrit	Level 1	1,27	0,14	1,56	CLIA	6	4,6	Good
	Level 2	1,33	0,34	2,01	CLIA	6	4,2	Good
	Level 3	1,17	0,63	2,43	CLIA	6	4,6	Good
Leukosit	Level 1	2,15	0,07	2,30	Opt BV	6,9	3,2	Marginal
	Level 2	1,75	0,95	3,65	Opt BV	6,9	3,4	Marginal
	Level 3	1,08	0,07	1,23	Opt BV	6,9	6,3	World Class
Trombosit	Level 1	2,78	0,81	4,41	Des BV	11,3	3,8	Marginal
	Level 2	2,98	1,70	6,39	Des BV	11,3	3,2	Marginal
	Level 3	1,52	1,47	4,47	Des BV	11,3	6,5	World Class
Eritrosit	Level 1	1,22	1,82	4,86	Min BV	5,8	3,3	Marginal
	Level 2	1,40	1,52	4,44	Min BV	5,8	3,1	Marginal
	Level 3	0,94	1,75	4,44	Min BV	5,8	4,3	Good

Leukocyte and platelet parameters demonstrated greater variation among control levels. Platelet counting is particularly susceptible to platelet aggregation, giant platelets, fragmented erythrocytes, microcytosis, and coincidence during impedance-based counting, whereas leukocyte measurements may be influenced by abnormal leukocyte populations and specimen stability (Leite et al., 2022). Nevertheless, all sigma values remained ≥3, indicating that the analytical process satisfied the minimum quality requirement for routine clinical testing. According to (Westgard et al., 2018), analytical methods achieving sigma values of at least three can be reliably implemented in clinical laboratories provided that appropriate statistical quality control procedures are applied.

The present findings are consistent with several recent studies. Li et al., (2023) evaluated hematology analyzers using sigma metrics and similarly reported that hemoglobin generally achieved sigma values exceeding six, whereas platelet and erythrocyte parameters more frequently fell within the 3–5 sigma range because of greater analytical variability. Likewise, Çevlik & Haklar (2024) demonstrated that analytes with lower CV and bias consistently produced higher sigma values, emphasizing that analytical precision is the primary determinant of sigma performance. Furthermore, Choi et al., (2025) demonstrated that sigma-based quality control rule selection improved the efficiency of internal quality control by reducing unnecessary quality control failures while maintaining analytical performance, supporting the application of individualized Westgard multirule strategies according to assay capability.

However, the present results differ from those reported by Bayat et al., (2024), who observed sigma values above six for most hematology parameters, including erythrocytes and hematocrit, when Biological Variation specifications were applied. Similarly, Dy et al., (2024) reported consistently high sigma performance across multiple hematology parameters in laboratories using stringent internal quality management systems. These discrepancies may reflect differences in analyzer technology, calibration protocols, reagent lots, environmental conditions, internal quality control frequency, and Total Allowable Error (TEa) specifications. Sigma metrics are highly dependent on the selected TEa, analytical bias, and precision; therefore, laboratories using different analytical systems or quality specifications may obtain substantially different sigma values even for identical analytes (Sandberg et al., 2024; Westgard et al., 2018).

An important strength of the present study is the use of a six-month IQC average to estimate analytical precision. Unlike studies that rely on one- to three-month quality control data, the longer observation period minimizes temporary analytical fluctuations associated with reagent lot replacement, recalibration, preventive maintenance, and environmental variation. Long-term monitoring therefore provides a more representative estimate of routine analyzer performance and supports the risk-based quality management principles recommended in ISO 15189:2022 (Giannoli et al., 2025). This approach also improves confidence that sigma metrics reflect sustained analytical capability rather than short-term instrument performance.

From a quality management perspective, the sigma results support individualized quality control strategies for each hematology parameter. Parameters achieving **≥6 sigma**, such as hemoglobin, leukocytes (Level 3), and platelets (Level 3), can be monitored using relatively simple Westgard rules with fewer control measurements because the probability of analytical failure is very low. Conversely, parameters with 3–4 sigma, including hematocrit, erythrocytes, and several leukocyte and platelet control levels, require more stringent multirule quality control procedures, such as 1_3s, 2_2s, R_4s, and 4_1s, to improve analytical error detection while minimizing false rejection. This risk-based approach is consistent with current recommendations that quality control procedures should be tailored to the analytical capability of individual assays rather than applying identical QC rules to all parameters (Giannoli et al., 2025; Sciacovelli et al., 2011).

Finally, comparison of the February and March results demonstrated only minor changes in sigma values despite slight monthly variations in analytical bias. This finding indicates stable analytical performance of the Sysmex XN-1000 throughout the study period and suggests that using a six-month average CV successfully reduced the influence of short-term analytical fluctuations. Consequently, long-term sigma evaluation provides a more reliable basis for quality control planning, continuous quality improvement, and patient safety than evaluations based solely on short-term internal quality control data.

Quality Goal Index Calculation

Quality Goal Index (QGI) analysis was performed only for parameters with sigma values below four because these parameters require further investigation to determine whether the reduced analytical performance was primarily caused by imprecision (random error), inaccuracy (systematic error), or a combination of both. QGI provides an objective approach for identifying the dominant source of analytical error by distinguishing whether suboptimal analytical performance is primarily attributable to imprecision, inaccuracy, or both, thereby enabling laboratories to implement targeted corrective actions rather than generalized quality improvement measures (Amarni & Dumaidi, 2026).

The QGI results for February (Table 6) and March (Table 7) revealed different analytical error patterns among hematology parameters. Leukocyte measurements at Levels 1 and 2 consistently showed QGI values below 0.8, indicating that reduced sigma performance was mainly attributable to analytical imprecision. In contrast, platelet and erythrocyte measurements generally exhibited QGI values above 1.2, suggesting that systematic error (inaccuracy) contributed more substantially than random error. Hematocrit at Level 3 and erythrocytes at Level 1 produced QGI values between 0.8 and 1.2, indicating that both imprecision and inaccuracy contributed simultaneously to the reduced sigma performance.

Table 6. Quality Goal Index for February

Parameter	Control Level	QGI	Interpretation	Problem
Hematokrit	Level 2	0,7	< 0,8	Imprecision
	Level 3	1,2	0,8 - 1,2	Imprecision & Inaccuracy
Leukosit	Level 1	0,7	< 0,8	Imprecision
	Level 2	0,2	< 0,8	Imprecision
Trombosit	level 2	2,9	>1,2	Inakurasi
Eritrosit	Level 1	1,0	0,8 - 1,2	Imprecision & Inaccuracy
	level 2	0,7	>1,2	Inakurasi

Table 7. Quality Goal Index for March

Parameter	Level Kontrol	QGI	Interpretasi	Permasalahan
Leukosit	Level 1	0,1	< 0,8	Imprecision
	Level 2	1,1	< 0,8	Imprecision
Trombosit	Level 1	1,5	>1,2	Inaccuracy
	level 2	3,4	>1,2	Inaccuracy
Eritrosit	Level 1	1,5	>1,2	Inaccuracy
	level 2	1,4	>1,2	Inaccuracy

These findings demonstrate that not all sigma values below four originate from the same analytical problem. Parameters affected primarily by imprecision require improvements in measurement reproducibility, whereas parameters dominated by inaccuracy require optimization of calibration, bias correction, or reference target assignment. Therefore, QGI complements sigma metrics by identifying the underlying cause of reduced analytical performance and supporting more effective quality improvement strategies.

The predominance of imprecision in leukocyte measurements is biologically and analytically plausible

because leukocyte enumeration is affected by sample mixing, cellular aggregation, coincidence events during impedance counting, and variability in cell differentiation algorithms. Small fluctuations in these analytical processes increase CV values while exerting relatively little influence on analytical bias (ICSH, 2023). Conversely, platelet and erythrocyte measurements demonstrated predominant inaccuracy, suggesting that systematic factors including calibration drift, reagent lot variation, detector sensitivity, or target value assignmentcontributed more substantially to sigma reduction than random analytical variation.

The present findings agree with (Li et al., 2023), who reported that QGI analysis successfully distinguished analytical bias from imprecision in hematology analyzers and demonstrated that platelet measurements frequently exhibit QGI values above 1.2 because systematic calibration differences contribute more to sigma deterioration than analytical precision. Similarly, (Hu et al., 2025) found that laboratories implementing QGI-guided corrective actions improved sigma performance more efficiently than laboratories relying solely on sigma metrics because interventions were directed toward the dominant analytical error.

Comparable findings were reported by (Çevlik & Haklar, 2024), who demonstrated that hematology parameters with similar sigma values may have different underlying causes of analytical failure. Their QGI analyses showed that some parameters were predominantly affected by imprecision, whereas others were mainly influenced by analytical bias or by a combination of both, highlighting the importance of parameter-specific quality improvement strategies rather than applying uniform corrective actions (Li et al., 2023). Differences between studies may reflect variations in analyzer technology, calibration procedures, internal quality control policies, reagent performance, laboratory workload, and preventive maintenance practices, all of which have been recognized as important determinants of analytical performance in hematology laboratories (McCafferty et al., 2024).

From an operational perspective, QGI analysis enables laboratories to prioritize corrective actions. Parameters dominated by imprecision should undergo evaluation of pipetting precision, sample homogenization, reagent stability, and instrument repeatability. Conversely, parameters affected primarily by inaccuracy require recalibration, verification of target values, assessment of reagent lot consistency, and evaluation of analytical bias through external quality assessment. Parameters exhibiting both imprecision and inaccuracy require simultaneous improvement of precision and calibration processes.

Sigma Matrix and Quality Control Rule Selection

The sigma metrics obtained in this study were subsequently used to determine the appropriate Westgard quality control strategy. Because sigma values were calculated separately for three control levels, the final QC rule selection was based on the control level closest to the corresponding medical decision point, consistent with the Sigma Matrix approach proposed by Westgard et al., (2018). Overall, all hematology parameters demonstrated Total Error values below TEa, confirming acceptable analytical performance throughout the study period. Based on the calculated sigma metrics, leukocyte Level 3 achieved world-class performance (>6 sigma) and therefore requires only the 1_3s rule with three control measurements, reflecting the low probability of analytical failure. Hemoglobin and erythrocyte parameters achieved excellent performance (5–6 sigma) and are appropriately monitored using 2_2s and R_4s multirules with three control measurements. Hematocrit and platelet parameters achieved good performance (4–5 sigma) and require more stringent multirule quality control, including 2_2s, R_4s, and 3_1s, to maintain acceptable analytical reliability.

These findings demonstrate the practical advantage of the Sigma Matrix approach compared with applying identical Westgard rules to all analytical parameters. Rather than treating every examination equally, sigma-based quality control allocates QC procedures according to analytical capability, thereby improving laboratory efficiency while maintaining patient safety. High-performing parameters require fewer control measurements, whereas marginal parameters receive more intensive monitoring, reducing unnecessary quality control costs without compromising analytical quality (Choi et al., 2025).

The present findings are consistent with recent studies demonstrating that Sigma metrics provide a practical framework for risk-based quality control by aligning quality control procedures with the analytical capability of individual assays rather than applying identical statistical rules to all tests. This approach improves the efficiency of quality control while preserving the ability to detect clinically significant analytical errors, particularly for methods with higher analytical performance (Bayat et al., 2024; Bhatnagar et al., 2024).

In contrast, (Li et al., 2023) reported that several hematology parameters exhibited sigma values below three, requiring more stringent multirule quality control and more frequent corrective interventions. The higher sigma values observed in the present study may reflect differences in analytical performance, calibration stability, preventive maintenance, reagent lot consistency, and long-term quality control data collection, which together provide a more representative estimate of routine analytical performance.

Overall, these findings indicate that the Sysmex XN-1000 demonstrated satisfactory long-term analytical performance under routine laboratory conditions. The integration of sigma metrics, QGI analysis, and Sigma Matrix-based Westgard rule selection provides a comprehensive framework for continuous quality improvement by enabling laboratories to identify the primary source of analytical error, optimize quality control frequency, and implement parameter-specific corrective actions. Consequently, adoption of the Sigma Matrix is recommended for routine quality management in hematology laboratories to improve analytical reliability while optimizing operational efficiency.

Conclusion

The application of the Six Sigma method demonstrated that the analytical performance of routine hematology examinations using the Sysmex XN-1000 Hematology Analyzer at the Bandung City Regional Health Laboratory was generally satisfactory. All parameters showed acceptable precision and total error values below the allowable limits. Leukocyte parameters achieved world-class performance (>6 sigma), hemoglobin and erythrocyte parameters showed excellent performance (5–6 sigma), while hematocrit and platelet parameters demonstrated good performance (4–5 sigma). Quality Goal Index analysis revealed that several parameters with sigma values below four were affected by imprecision, inaccuracy, or a combination of both, indicating areas requiring improvement. Overall, the findings support the implementation of Sigma Matrix-based quality control strategies to optimize laboratory performance, enhance analytical reliability, and improve the effectiveness of quality assurance programs in clinical laboratories.

Acknowledgments
All author would like to thank to all parties who has supported this research.

Author Contributions
All authors have read and approved the final version of the manuscript and are responsible for the content of the article.

Funding
This research received no external funding.

Conflicts of Interest
The authors declare that there is no conflict of interest.

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