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Internal Quality Control on Leukocyte Count at UPTD Health Laboratory, Sleman, DIY

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ABSTRACT

Background: Hematology analyzers (HA) are used for automated leukocyte counts, but are subject to errors if nucleated erythrocytes, fibrin precipitation, or prolonged sample sitting are present. Quality control is required to ensure accuracy of results. The clinical laboratory of the UPTD Health Laboratory of Sleman Regency, DIY has carried out quality control but has not involved Levey-Jennings control charts and six sigma analysis. This study aims to determine the internal quality assurance of the analytical stage of the HA device in the examination of leukocyte counts in that laboratory.

Methods: This type of research is a descriptive study with the subject of the HA Sysmex XP-100 tool. The variables of this study are data from the quality control results of automatic leukocyte count examination in February-March 2024. Data analysis includes calculation of six sigma values, creation of Levey-Jennings control charts and evaluation using westgard rules.

Results: The results showed that the examination of the number of leukocytes with the HA tool had an accuracy of 99.45% and a precision of 98.49%, while for the evaluation of the Levey-Jennings graph with the westgard rule at the normal level control, there was a rule of 12s on day 3 and 13s on day 6. Six sigma analysis shows that the performance of the tool for examining the number of leukocytes is at world class level with an average sigma value of 12.42.

Conclusion: This Based on the results, it can be concluded that the examination of leukocyte counts with the HA Sysmex XP-100 at the Sleman Regency Health Laboratory UPTD, DIY has an accuracy of 99.45% and a precision of 98.49%. Evaluation of the Levey-Jennings control chart and Six Sigma analysis showed world-class performance, indicating that this tool provides excellent performance and meets international quality standards.

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INTRODUCTION

The clinical laboratory is a part of health services that plays a role in diagnosis by carrying out tests on hematology, clinical chemistry, immunology, parasitology, microbiology, or other areas of human health (1). The implementation of high-quality clinical laboratories to support efforts to improve public health standards, quality results is very important. Improving the quality of service and the quality of laboratory examination results are two important steps taken to anticipate this incident. Quality control which includes

quality assurance needs to be implemented in order to provide accurate results (2).

The process or all actions taken to ensure the thoroughness and accuracy (precision and accuracy) of examination results is known as laboratory quality assurance. One of the aspects included in laboratory quality assurance is internal quality assurance (IQA). IQA is a continuous prevention and monitoring process carried out by each laboratory to reduce the possibility of errors and ensure accurate examination results (3).

Strengthening the internal quality of clinical laboratories covers all laboratory examination services, one of which is in the field of hematology. Examination of red blood cells (RBC), hemoglobin (Hb), hematocrit (Hct), white blood cells (WBC), and platelet count are some of the hematological examination parameters (4). Hematology examinations currently use automated methods and tools, namely hematology analyzers. A hematology analyzer is an automatic blood cell counting tool with a number of parameters that can be checked simultaneously (5).

Even though it is easy to use, the Hematology Analyzer has limitations. If the sample is left too long, there is fibrin deposition, or there are nucleated erythrocytes, this instrument can read leukocytes incorrectly (6). Leukocyte count examination is a hematological examination parameter that has a total allowable error (TEa) value of 15% determined by the Clinical Laboratory Improvement Amendments (CLIA). When compared with other parameters such as erythrocyte count, hematocrit and hemoglobin, this parameter is the one with the Tea highest value. A large TEa value indicates that there are many error factors in examining the leukocyte count (Westgard, 2023). Therefore, quality control of the hematology analyzer is needed to ensure the results are accurate (7).

The process of achieving standards of accuracy and precision at the analytical stage is known as quality control. The goal of quality control is to identify errors, both random and systematic, at the analytical stage (2). Westgard and six sigma rules can also be used to check quality control apart from accuracy and precision (8).

Westgard provides a number of rules to assist in the evaluation of control chart examinations. By using appropriate control rules, any errors can be detected early (9). Sigma metric analysis is a laboratory quality control and improvement method that provides explanations for deviations and shows the frequency of errors in each process. The six-sigma scale consists of a range of 1 to 6. Calculating Defects Per Million Opportunities (DPM, also known as DPMO) is a way to assess sigma performance (10).

Based on research conducted by Fuadi (2019), the average sigma value for leukocyte examination at all levels was 7.26. The sigma value in clinical laboratory practice is included in world class performance (11). In research conducted by Maharani (2022), the results obtained on the WBC parameters (low, normal, high levels) had an average sigma value > 6 (world class performance) (12).

RESEARCH METHODS

This research is a descriptive study with data sources from the test results of control materials when examining leukocyte counts using the Sysmex XP-100 Hematology Analyzer. The control materials used were 3 levels of control materials (low, normal and high) which were carried out in February-March 2024 in the UPTD clinical laboratory of the Sleman Regency Health Laboratory, DIY.

The analysis method used is the Westgard multirule system and six sigma. The preliminary period was carried out by taking 21 data at 3 levels of control materials (7 data each). The preliminary period was carried out to calculate the average value, standard deviation (SD), coefficient of variation (CV), bias, % bias, total error (TE) %, the total allowable error (TEa) value used was 15% (CLIA) and six sigma value. The sigma value obtained is used to determine the quality of leukocyte count examination in the laboratory (scale 1-6). The Levey-Jennings control graph is created using the results of the average and SD calculations from the preliminary period, then evaluated using the Westgard rule.

RESULTS

This research was carried out on February 16-March 19 2024 in the UPTD clinical laboratory of the Sleman Regency Health Laboratory, DIY. The data taken in this study are the results of control material examination in the automatic leukocyte count examination using the Sysmex XP-100 Hematology Analyzer using 3 levels of control material in February-March 2024. The true value, mean range and control range data for leukocyte count examination are based on Insert kits of control materials are presented in Table 1.

The preliminary period is carried out by taking 21 control data for leukocyte count examinations carried out on February 16-March 2 2024. Preliminary test calculations can be carried out with a minimum amount of data of 20 data (13). Data on the results of counting the number of leukocytes for the control material in the preliminary test can be seen in table 2.

Table 1. True Value, Mean Range and Control Range in Leukocyte Count Examination (kit insert)

No. Lot	Control Level	*True Value* (×10³/µL)	*Mean Range* (×10³/µL)	*Control Range* (×10³/µL)
40270821	Low	3,3	±0,4	2,9-3,7
40270822	Normal	7,5	±0,5	7,0-8,0
40270823	High	17,6	±1,2	16,4-18,8

Table 2. Results of Examination of Leukocyte Counts from Control Materials in Preliminary Tests

No.	Date	Level 1 (Low) (×10³/µL)	Level 2 (Normal) (×10³/µL)	Level 3 (High) (×10³/µL)
1	16 Feb 2024	3,2	7,6	17,7
2	19 Feb 2024	3,3	7,6	17,8
3	20 Feb 2024	3,4	7,5	17,6
4	22 Feb 2024	3,2	7,7	17,6
5	26 Feb 2024	3,4	7,6	17,3
6	1 Mar 2024	3,2	7,6	17,6
7	2 Mar 2024	3,3	7,5	17,7

Table 2 presents data on the results of the hematology analyzer control material examination when examining the leukocyte count for the preliminary test. Preliminary tests were carried out to calculate the average value, standard deviation (SD), coefficient of variation (CV), bias, % bias, total error (TE) % and six sigma values, while the TEa value used was 15% for examining the number of leukocytes obtained from the CLIA reference. Data on the results of the QC examination of the number of leukocytes in the preliminary test can be seen in table 3.

Table 3. Quality Control Examination Results Data on Leukocyte Counts in Preliminary Tests

	Level 1 (Low)	Level 2 (Normal)	Level 3 (High)
True Value (×10³/µL)	3,30	7,50	17,60
Rata-rata (×10³/µL)	3,29	7,59	17,61
Standar Deviasi	0,09	0,07	0,16
Koefisien Variasi	2,74	0,91	0,89
Bias	0,01	0,09	0,01
% Bias	0,43	1,14	0,08
TE (%)	5,91	2,96	1,87
TEa (%)	15	15	15
Sigma	5,32	15,23	16,70

Based on table 3, the average value compared with the control range (table 1) shows that the overall QC data for examining the number of leukocytes in the preliminary test is in the "in control" category. The SD values of the three control levels in the table above show that each control material measurement is not

much different from the average value. The standard CV and % bias values for examining leukocyte counts are <5% and 4.4% (7,9,14). The CV and % bias values of the three control levels in the table above show results that do not exceed standard values. The TE values of the three control levels in the table above show results that do not exceed the TEa value (15%) which indicates that the total error (TE) is still within tolerable limits. The six sigma values that have been analyzed show sigma values >6 at normal and high levels (world class) and 5.32 at low levels (excellent).

Table 4. Average QC Examination Results Data for Leukocyte Counts in Preliminary Tests

	Level1 (Low)	Level 2 (Normal)	Level 3 (High)	Rata-Rata
Koefisien Variasi	2,74	0,91	0,89	1,51
% Bias	0,43	1,14	0,08	0,55
Sigma	5,32	15,23	16,70	12,42

Table 5. Levey-Jennings Chart for Control Material Leukocyte Count Examination Results

No.	Tanggal	Level 1 (Low) ($\times 10^3/\mu L$)	Level 2 (Normal) ($\times 10^3/\mu L$)	Level 3 (High) ($\times 10^3/\mu L$)
1	4 Maret 2024	3,2	7,6	17,7
2	7 Maret 2024	3,3	7,6	17,6
3	12 Maret 2024	3,2	7,4	17,5
4	16 Maret 2024	3,3	7,5	17,6
5	18 Maret 2024	3,2	7,7	17,7
6	19 Maret 2024	3,3	7,8	17,9

Table 5 presents the leukocyte count examination data which will be used as a control period to be created into the Levey-Jennings control chart. The graph was created using the results of calculating the average and SD from the preliminary period, then evaluated using Westgard's rules. The Levey-Jennings control chart for checking leukocyte counts for all levels of control material can be seen in Figure 1. The results of evaluating the Levey-Jennings control chart using the Westgard rule for examining leukocyte counts are presented in table 6.

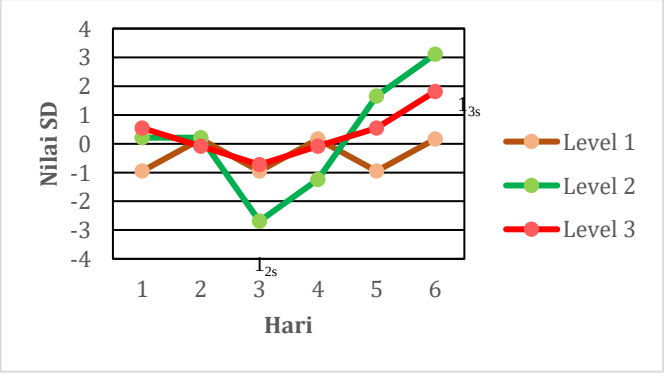

Figure 1. Levey-Jennings Control Chart for Leukocyte Count Examination

Table 6. Evaluation Results of Levey-Jennings Control Charts using Westgard's Rules

day	Low	Normal	High	interpretation
3	-	1_{2s}	-	Warning rules

6	-	1_{3s}	-	Random error

DISCUSSION

Standard deviation (SD) is a description of the distribution of data in a sample examination result against the average value (mean) which shows how far or how close it is from the mean value (9). The SD value obtained in this study was 0.09 for low level, 0.07 for normal level and 0.16 for high level (table 3). These results show that the data distribution is very close to the mean value, which means that each measurement of the control material is not much different. SD is a measure of variability or diversity associated with random error or imprecision. A small SD value indicates that the data tends to be very close to the mean, while a large SD value indicates that the data is spread across a wide range of values (8).

The coefficient of variation (CV) is a relative measure of the variability of results and is expressed in units of percent. CV is used to measure precision (9). The smaller the CV value (%) the more precise the system/method. Conversely, the greater the CV value (%) the less precise the system/method is. Ideally the CV (impression) value should be lower than 5% or the precision value higher than 95% (9,14). In this study, the CV value obtained when examining the leukocyte count was 2.74% for low levels, 0.91% for normal levels and 0.89% for high levels (table 3) with an average CV value of 1.51 % (table 4) and the precision value is 98.49%. From these results it is known that none of the CV values exceeds the 5% limit and the precision value is higher than 95%. This shows that the level of accuracy of the tool for examining leukocyte counts has high precision.

Bias (inaccuracy) is a deviation or difference in the results of measurements made from the target value of a control material whose value is already known and expressed in percent units. Bias is used to measure accuracy (9). The smaller the d% (bias), the higher the accuracy of the examination (15). In this study, the bias value obtained was 0.43% for low levels, 1.14% for normal levels and 0.08% for high levels (table 3) with an average bias value of 0.55% (table 4) and the accuracy value is 99.45%. The standard bias value (d%) for the number of leukocytes is 4.4% or the accuracy value is higher than 95.6% (7). These results show that the results of the leukocyte count examination carried out by the hematology analyzer have a very good level of accuracy because the results of the bias value do not exceed 4.4% and the accuracy value is higher than 95.6%.

Total error (TE) is a combination of systematic error (bias or inaccuracy) and random error (CV or impression), while total allowable error (TEa) is the maximum error or deviation (TE) that can still be tolerated, which is considered not to interfere with a clinical decision. (9,10). The TEa value used in leukocyte examination is 15% referring to the Clinical Laboratory Improvement Amendments (CLIA). The TE value obtained in this study was 5.91% for low level, 2.96% for normal level and 1.87% for high level (table 3) with an average value of 3.58%. These results show that the total error made by the hematology analyzer for leukocyte count testing is still within acceptable limits because the TE results at all control levels are still below the TEa value.

Evaluation of the Levey-Jennings control chart of the leukocyte count, showed that there were control values (normal level) where deviations occurred, namely the 1_{2s} rule on the third day. This rule occurs if one control value is outside the ±2 SD limit, but still within the ±3SD limit (warning rule) (16). This is a warning of a problem with the instrument or a method malfunction. The solution to the 1_{2s} rule is that if you use two or three different control levels, you have to see whether the other control level values are also outside the ±2SD limit. If the control values at other levels are outside the ±2SD limit (both +2SD or -2SD), then the problem must be resolved before providing patient care. However, if the control values at other levels are within ±2SD, then the instrument can still be used for patient care (9).

At normal levels there are also deviations, namely the 13s rule on the sixth day. This rule occurs if a single control value is outside the ±3SD limit. This rule detects random errors. The instrument should not be used for patient care until the underlying problem is resolved. Random errors occur due to variations that cannot be controlled by the individual making the measurement. Random errors can be caused by several factors such as imperfect mixing (homogenization), variations in incubation time, calibration variations, and operator variations. (9).

Apart from using Levey-Jennings control charts and Westgard rules, quality control (QC) assessments can also be carried out by assessing sigma metric (six sigma) values. Sigma metrics have a scale of 1-6 sigma values which are used to measure tool performance. The six sigma values and their levels in clinical laboratory practice are world class level for sigma 6, excellent for sigma 5, good for sigma 4, marginal for sigma 3 , poor for a sigma value of 2 and unacceptable for a sigma value of 1 (11).

The six sigma value of leukocyte count examination in this study resulted in 5.32 for low levels, 15.23 for normal levels, and 16.70 for high levels (table 3) with an average sigma value of 12.42 (table 4). Based on these results, it is known that the leukocyte count examination (normal and high levels) has a sigma value of >6 (world class) where the hematology analyzer only has 3.4 errors per one million opportunities (3.4 DPMO). Examination of the leukocyte count (low level) had a sigma value of 5.32 (excellent) where the

hematology analyzer only had 233 errors per one million opportunities (233 DPMO).

CONCLUSION

The use of the Sysmex XP-100 Hematology Analyzer shows an excellent level of accuracy with accuracy reaching 99.45% and a high level of precision of 98.49%. Evaluation of the Levey-Jennings control chart using the Westgard rule shows that there is a deviation from the normal control level with the 12s rule occurring on the 3rd day and the 13s rule on the 6th day. Six sigma analysis confirms that the performance of this tool is at world class level with an average sigma value of 12.42. These results provide confidence that the Sysmex XP-100 Hematology Analyzer can be relied on for examining leukocyte counts in accordance with applicable international standards.

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