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Test Results Of Quality Control Examination Of Erythrocytes (RBC), Hemoglobin (HB) And Thrombocytes (PLT) Using The Six Sigma Method At UPTD RSUD

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ABSTRACT
Hospital quality must be improved to maintain the quality of service to patients. One of the laboratory tests is hematology examination. Hematology examination has used Automatic Hematology Analyzer. To ensure the accuracy, precision and accuracy of laboratory examinations, Quality Control is needed. Six Sigma is a metric that measures process performance as the level of Defects Per Million Opportunities (DPMO), DPMO is one of the Process Capability assessments to measure how good a production process is on a scale of 1-6. To determine the quality of tools using the Six Sigma method. The research was conducted at UPTD RSUD X by taking data from Quality Control results, the data was analyzed using six sigma so that this research is a descriptive observational research and the nature of this research is Retrospective Cross-sectional. The average control results in March for low, normal, and high erythrocyte level examinations were 2.21, 4.16, and 4.91. The average control results for platelet parameters were 53.74, 266.65, and 486.97. and for hemoglobin parameters were 5.48, 11.80, and 15.22. In April, the average control results for erythrocyte parameters were 2.25, 4.19, 5.01, while the average control results for platelets were 50.07, 240.89, and 489.36. Then, the hemoglobin parameter showed an average control result of 5.56, 11.94, and 15.65. The control results for each parameter are still acceptable because based on the Westgard rules, no control results exceed 3SD.

INTRODUCTION

Hospital quality must be improved for the benefit of patients, because the main task of a hospital or health care facility is to provide medical services to patients. This requires proper management, including laboratories. Improving laboratory quality must be based on laboratory management so that the accuracy and precision of laboratory results are well received by patients. In laboratory operations, attention must be paid to the quality of service.(Hadi et al., 2023).

Laboratory services are an integral part of health services needed to support efforts to improve health. Therefore, laboratory examination results must be guaranteed in quality (Rifqi, 2014 inWoelansari et al., 2019).

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One of the laboratory tests is a hematology test. Hematology tests consist of several types of tests including Erythrocyte (RBC), Hemoglobin (Hb) and Platelet (PLT) tests. Hemoglobin is a complex protein that binds iron (Fe) and is found in Erythrocytes. The main function of Hemoglobin is to transport oxygen (O2) from the lungs throughout the body and exchange it with carbon dioxide (CO2) from the tissues to be excreted through the lungs (Ifan, 2018). Erythrocytes are the largest cell components in the blood. Erythrocytes are shaped like biconcave discs with a diameter of about 7.5 μm, a thickness of about 2.6 μm at the edge and 0.75 μm in the middle. Because of their relatively uniform size and shape and almost all body tissues contain erythrocytes, histology experts usually use erythrocytes as a standard to estimate the size of other adjacent cells. Platelets are cell fragments with very small sizes, shaped like plates with a diameter of about 2-4 μm. Platelets play an important role in the process of blood clotting and repair of blood vessels that have minor damage, thus preventing blood loss from the vessels (Mescher, 2015).

Hematology examination has used the Automatic Hematology Analyzer tool. Examination with an automatic tool will produce very fast results. To ensure the accuracy, precision and precision of laboratory examinations, Quality Control (QC) is needed.(Jemani et al., 2019).

*Quality control (QC)*is a process or stage in a procedure carried out to evaluate the testing process, with the aim of ensuring that the quality system is running properly and is carried out with the aim of guaranteeing laboratory examination results, knowing and minimizing deviations and knowing the source of deviations (Rinaldi, 2015 inJemani et al., 2019). In order for the results of the tool to be reliable, it is necessary to carry out Quality Control on the Hematology Analyzer tool to find out if there are any measurement deviations on the tool.(Vis, et al. , 2016).

Six Sigma is a metric that measures process performance as a level of Defects Per Million Opportunities (DPMO), DPMO is one of the Process Capability assessments to measure how well a production process is. to find and eliminate defects and variations in a process. The Sigma scale is divided into a range of 1-6 (S. Westgard, 2020 inPrasetya et al., 2021). Six Sigma values can change depending on the control materials used.(Jawahar et al., 2016).

The use of Westgard multirule is common in clinical laboratories, but the Six Sigma method is still very rarely used. The use of six sigma is more often found in clinical chemistry examinations than hematology examinations.(Kumar et al., 2018).

The results of research conducted by(Prasetya et al., 2021)shows that at low level, a deviation of 13s (random error) is obtained. At normal level, a deviation of 12s (warning) is obtained. At high level, a deviation of 12s (warning) is obtained. The Sigma scale of the three control levels shows a scale above 6. Six Sigma analysis for leukocyte examination shows an average Sigma of 7.16 which shows that leukocyte examination using the Hematology Analyzer tool has an accuracy of 99.9%.

MATERIAL/METHOD

This study is a descriptive observational study. This study aims to determine the internal quality improvement of the analytical stage of the Hematology

Analyzer. Data collection was carried out in March and April from the results of the Quality Control of the Mindray BC-5380 Hematology Analyzer on the examination of Erythrocytes (RBC), Hemoglobin (Hb) and Platelets (PLT) with low, normal, and high level control materials so that the nature of this study is Retrospective Cross-sectional. The data were analyzed using the Westgard and six sigma rules. Westgard analysis is presented in a Quality Control graph and read using the Westgard rules to find out whether there are any deviations. The sigma value obtained is used to determine the quality of laboratory equipment (scale 1-6).

The population in this study was the Quality Control data of the Mindray BC - 5380 hematology analyzer at the UPTD Laboratory of RSUD X. The samples in this study were control materials for low, normal and high parameters of Erythrocytes (RBC), Hemoglobin (Hb) and Platelets (PLT) during March and April with a total of 59 samples. The independent variable in this study was the use of the Mindray BC-5380 hematology analyzer.

The dependent variable in this study is the QC result data for the use of three levels of control materials (Low, Normal and High) for examining Erythrocytes (RBC), Hemoglobin (Hb) and Platelets (PLT) during March and April for 59 samples.

The research data is secondary data taken from the Quality Control results data which is carried out once every day before analysis with samples. Control data includes low, normal, and high control material levels, with the types of parameters analyzed being Erythrocytes (RBC), Hemoglobin (Hb) and Platelets (PLT). The internal quality assurance analysis method is carried out with Westgard and six sigma.

RESULTS AND DISCUSSION

The study was conducted at the UPTD RSUD X Laboratory from March to April with a total of 59 controls carried out once a day. This study aims to determine the use of Six Sigma as a method to test the results of the Quality Control of the Hematology Analyzer tool at the UPTD RSUD X Laboratory for examining the number of Erythrocytes (RBC), Hemoglobin (Hb) and Platelets (PLT). The population in this study was the Quality Control data of the Mindray BC - 5380 hematology analyzer at the UPTD RSUD X Laboratory. The data obtained were calculated to obtain true value data, average, SD, CV, Bias, TE, TEA, which would then be analyzed using Six Sigma.

Table 1. Standard Values for Control Materials for Examination of Erythrocytes (RBC), Hemoglobin (HB) and Platelets (PLT) in March and April.

No	True Value	Average Range	Level	Information
1	57	±4	Low	Hemoglobin
2	121	±6	Normal	Hemoglobin
3	157	±8	High	Hemoglobin
4	2.18	±0.18	Low	Erythrocytes
5	4.07	±0.24	Normal	Erythrocytes
6	4.86	±0.30	High	Erythrocytes
7	48	±20	Low	Platelets

8	241	±40	Normal	Platelets
9	489	±60	High	Platelets

In hemoglobin control, the true values obtained at low, normal, and high levels were 47, 121, and 157, respectively. These true value figures will be used to calculate the six sigma value for hemoglobin examination parameters. In the erythrocyte control, the true value obtained at low, normal, and high levels was 2.18, 4.07, and 4.86, respectively. The true value figures will be used to calculate the six sigma value for the erythrocyte examination parameters. In platelet control, the true values obtained at low, normal, and high levels were 48, 241, and 489, respectively. These true value figures will be used to calculate the six sigma value for platelet examination parameters.

The results of the Quality Control test results for March and April which were analyzed using the six sigma method can be seen in the table below:

Table 2. Preliminary Test Data for Hemoglobin (HB) Examination in the Month

Data analysis	**Level 1Low**	**Level 2 Normal**	**Level 3 High**
True Value	57	121	157
Average	5.48	11.80	15.22
Standard Deviation	0.08	0.20	0.32
Coefficient of variation	1.42	1.72	2.09
%Bias	-90.38	-90.25	-90.30
TE%	-87.54	-86.81	-86.13
TEA	7	7	7
Six Sigma	2.00	2.00	2.00

Based on the results of Hemoglobin quality control in the table above, the true values used at low, normal, and high levels are 57, 121, and 157, respectively. The average results of low, normal, and high level control are 5.48, 11.80, and 15.22, respectively. The Standard Deviation at each level is 0.08, 0.20, and 0.32 which are used to analyze the results of quality control. Referring to the results of the standard deviation, the results of quality control are still categorized as good.

The coefficient of variation of low, normal, and high level controls were 1.42, 1.72, and 2.09 respectively, indicating that the difference between the control results and the original values at low, normal, and high level controls were -90.38, -90.25, and -90.30 respectively, indicating that there was no significant difference. TE% of low, normal, and high level controls were -87.54, -86.81, and -86.13 respectively. The sigma value obtained for the hemoglobin parameter for each level was 2.00, indicating that the control results were not good.

Table 3. Preliminary Test Data for Erythrocyte (RBC) Examination in March

Data analysis	**Level 1 Low**	**Level 2 Normal**	**Level 3 High**
True Value	2.18	4.07	4.86

Average	2.21	4.16	4.91
Standard Deviation	0.03	0.05	0.08
Coefficient of variation	1.41	1.12	1.64
%Bias	1.18	2.24	1.08
TE%	4.00	4.49	4.37
TEA	6	6	6
Six Sigma	2.00	2.00	2.00

Based on the results of the quality control of the Erythrocyte examination in the table above, the True Value control of low, normal, and high levels are respectively 2.18, 4.07 and 4.86. The average results of the Erythrocyte control at low, normal, and high levels are respectively 2.21, 4.16, and 4.91, Standard deviation 0.03, 0.05, 0.08, while the coefficient of variation is 1.41, 1.12, 1.64. Referring to the results of the standard deviation, the results of quality control are still categorized as good.

The coefficient of variation of low, normal, and high level controls were 1.41, 1.12, and 1.64, respectively, indicating the difference between the control results and the original values at low, normal, and high level controls were 1.18, 2.24, and 1.08, respectively. TE% of low, normal, and high level controls were 4.00, -4.49, and 4.37, respectively. The Erythrocyte TEA value was obtained based on the CLIA standard for each level, which is 6. The sigma value obtained for this examination parameter for each level was 2.00, indicating poor control results.

Table 4. Preliminary Platelet Examination (PLT) Test Data in March

Data analysis	**Level 1Low**	**Level 2 Normal**	**Level 3 High**
True Value	48	241	489
Average	53.74	266.65	486.97
Standard Deviation	4.79	12.25	9.13
Coefficient of variation	8.91	4.59	1.88
%Bias	11.96	10.64	-0.42
TE%	29.78	19.83	3.34
TEA	25	25	25
Six Sigma	2.00	2.00	2.00

The results of the Platelet examination parameters in the table above obtained True Value control of low, normal, and high levels respectively are 48, 241 and 489. The average results of low, normal, and high level control are respectively 53.74, 266.65, and 486.97. The Standard Deviation at each level is 4.79, 12.25, 9.13. By referring to the results of the standard deviation, the results of the quality control of the platelet examination parameters are categorized as less good.

The coefficient of variation of low, normal, and high level controls were 8.91, 4.59, and 1.88, respectively, indicating the difference between the control results and the original values at low, normal, and high level controls were 11.96, 10.64,

and -0.42, respectively. TE% of low, normal, and high level controls were 29.78, 19.83, and 3.34, respectively. The Erythrocyte TEA value was obtained based on the CLIA standard for each level, which was 25. The sigma value obtained for the hemoglobin parameter for each level was 2.00, indicating poor control results.

Table 5. Preliminary Test Data for Hemoglobin (HB) Examination in April.

Data analysis	Level 1Low	Level 2 Normal	Level 3 High
True Value	57	121	157
Average	5.56	11.94	15.65
Standard Deviation	0.07	0.08	0.12
Coefficient of variation	1.22	0.69	0.79
%Bias	-90.24	-90.14	-90.03
TE%	-87.80	-88.75	-88.46
TEA	7	7	7
Six Sigma	2.00	2.00	2.00

In the Hemoglobin examination parameters, the True Value control of low, normal, and high levels was obtained, respectively, 57, 121, 157. The average of low, normal, and high level examinations, respectively, showed an average of 5.56, 11.94, and 15.65. The standard deviation is at 0.07, 0.08, and 0.12. Referring to the results of the standard deviation, the results of quality control are still categorized as good.

The coefficient of variation of low, normal, and high level controls were 1.22, 0.69, and 0.79, respectively, indicating the difference between the control results and the original values at low, normal, and high level controls were -90.24, -90.14, and -90.03, respectively. TE% of low, normal, and high level controls were -87.80, -88.75, and -88.46, respectively. The Erythrocyte TEA value was obtained based on the CLIA standard for each level, which is 7. The sigma value obtained for the hemoglobin parameter for each level was 2.00, indicating poor control results.

Table 6. Preliminary Test Data for Erythrocyte (RBC) Examination in April.

Data analysis	Level 1Low	Level 2 Normal	Level 3 High
True Value	2.18	4.07	4.86
Average	2.25	4.19	5.01
Standard Deviation	0.02	0.04	0.04
Coefficient of variation	0.68	1.00	0.84
%Bias	3.18	2.85	3.02
TE%	4.55	4.85	4.69
TEA	6	6	6
Six Sigma	2.00	2.00	2.00

In the erythrocyte examination parameters, the True Value control level low, normal, and high were respectively 2.18, 4.07, 4.86 on average at 2.25, 4.19, 5.01

so that the standard deviation was 0.02, 0.04, 0.04. By referring to the results of the standard deviation, the results of quality control are still categorized as good.

The coefficient of variation of low, normal, and high level controls were 0.68, 1.00, and 0.84, respectively, indicating that the difference between the control results and the original values at low, normal, and high level controls were 3.18, 2.85, and 3.02, respectively. TE% of low, normal, and high level controls were 4.55, 4.85, and 4.69, respectively. The Erythrocyte TEA value was obtained based on the CLIA standard for each level, which was 6. The sigma value obtained for the erythrocyte parameters for each level was 2.00, indicating that the control results were not good.

Table 7. Preliminary Test Data for Thrombocyte Examination (PLT) in April.

Data analysis	Level 1Low	Level 2 Normal	Level 3 High
True Value	48	241	489
Average	50.07	240.89	489.36
Standard Deviation	2.55	6.38	6.69
Coefficient of variation	5.10	2.65	1.37
%Bias	4.32	-0.04	0.07
TE%	14.51	5.25	2.81
TEA	25	25	25
Six Sigma	2.00	2.00	2.00

In the platelet examination parameters, the True Value control of low, normal, and high levels was obtained, respectively, 48, 241, and 489. The average results of low, normal, and high levels of control were respectively 50.07, 240.89, and 489.36 with standard deviations of 2.55, 6.38, and 6.69. Referring to the standard deviation results, in the low category, the control results can still be said to be acceptable with a warning. While in the normal and high categories, the control results were considered less good.

The coefficient of variation of low, normal, and high level controls were 5.10, 2.65, and 1.37, respectively. The %Bias indicating the difference between the control results and the original values at low, normal, and high level controls were 4.32, -0.04, and 0.07, respectively. The TE% of low, normal, and high level controls were 14.51, 5.25, and 2.81, respectively. The TEA value of Erythrocytes was obtained based on the CLIA standard for each level, which was 25. The sigma value obtained for the hemoglobin parameter for each level was 2.00, indicating poor control results.

DISCUSSION

Efforts to obtain quality laboratory examination results require a health laboratory quality assurance activity that is intended to ensure the accuracy and precision of laboratory examination results. The achievement of research results is compared with the control value of each examination parameter. The determination of the control value obtained from the party producing the control material, in this

case we use the production control from Mindray, namely the BC - 5380 hematology analyzer.

Errors in the analytical phase are less common compared to the pre-analytical stage, especially since more stable and standardized automation tools have been used. However, errors in the analytical stage can occur if there is still a lack of quality control processes carried out by a clinical laboratory. Six sigma measurement is an important assessment in quality control that can evaluate the process because it involves calculating CV, TEA and bias which describe the precision and accuracy of each examination parameter. Six sigma analysis is carried out to evaluate the quality control stage through statistical calculations(Hidayati & Maradhona, 2018).

Conventional definition of quality usually describes the direct characteristics of a product, such as performance, reliability, ease of use, aesthetics and so on. Therefore, quality is basically keeping promises to customers so that the party served feels satisfied and expressed through customer satisfaction tests and indeed patients are truly satisfied with the service. Quality has a very close relationship with customer satisfaction, namely quality provides an encouragement to customers to undergo a strong relationship with the company. In the long term, this kind of bond allows companies to understand customer expectations and their needs carefully. Thus, companies can increase customer satisfaction, which in turn can create loyalty or loyalty to companies that provide quality service.

From the research conducted in March 2024, the average results of Erythrocyte control at low, normal, and high levels were 2.21, 4.16, and 4.91, respectively, Standard deviation 0.03, 0.05, 0.08, while the coefficient of variation 1.41, 1.12, 1.64, it is said to have good accuracy. The sigma value obtained for this examination parameter for each level is 2.00. Thus, according to the provisions of six sigma, the limit for using the tool is for 10 patients in each control.

Furthermore, in the hemoglobin examination parameters, the average results of low, normal, and high level controls were 5.48, 11.80, and 15.22, respectively. The Standard Deviation at each level was 0.08, 0.20, and 0.32. The sigma value obtained for the hemoglobin parameter for each level was 2.00.

Platelet examination parameters, the average results of low, normal, and high level controls were 53.74, 266.65, and 486.97, respectively. The Standard Deviation at each level was 4.79, 12.25, 9.13. The sigma value obtained for the hemoglobin parameter for each level was 2.00.

The results of the control that has been done in April, for the examination of low, normal, and high hemoglobin levels, respectively showed an average of low, normal, and high level examinations, respectively showed an average of 5.56, 11.94, and 15.65. The standard deviation is at 0.07, 0.08, and 0.12 so that the control results are still said to have good accuracy. The sigma value obtained for the hemoglobin parameter for each level is 2.00.

Meanwhile, in the control results of erythrocyte parameters, the average is at 2.25, 4.19, 5.01 so that the standard deviation is 0.02, 0.04, 0.04. so it is said that the control results have good accuracy. The sigma value obtained for the hemoglobin parameter for each level is 2.00.

Meanwhile, in the platelet parameters, the average results of low, normal, and high level control were 50.07, 240.89, and 489.36, respectively, with standard deviations of 2.55, 6.38, and 6.69. So the accuracy of these parameters is classified

as poor. The sigma value obtained for the hemoglobin parameter for each level is 2.00.

Sigma values are created on a scale of 0 to 6. The sigma value indicates how many errors occur. The higher the sigma value, the more accurate the laboratory results. A sigma value of less than three is an indication of poor workmanship. While good workmanship is indicated by a sigma value of more than three. A sigma value of 6 or greater indicates excellent performance.(Adiga et al., 2015). A low sigma value of less than three indicates that action should be taken to improve analytical quality or the laboratory should use alternative reagents and methods.(Mao et al., 2018). Low sigma values can occur due to several factors, including differences in analyzer performance, poorly stored inspection reagents and control reagents, failure to perform routine maintenance, routine control, and the competence of laboratory staff.(Teshome et al., 2021).

Rejection based on the Westergard rule is if the control result exceeds 3SD. In the control that has been carried out, there are control results that exceed these provisions which indicate that the precision of the tool is not appropriate. If this happens, then a re-control needs to be carried out. The research that has been carried out shows that every control result that has been carried out is still included in the safe category (Entry control) with a warning(Prasetya et al., 2021).

CONCLUSION

Based on the six sigma analysis, the standard deviation of each control result shows good to very good accuracy. Then the calculation result of the sigma value shows a value of 2 which means that the control work is not good. The control results of each parameter are still acceptable because based on the Westgard rule, no control results exceed 3SD.

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