

DIFFERENCES IN MATERIAL QUALITY CONTROL EXAMINATION RESULTS ON HEMATOLOGY ANALYZER EQUIPMENT BEFORE AND AFTER PASSING THE OPEN STABILITY PERIOD

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ABSTRACT

Background : Internal Quality Improvement (PMI) is a preventive and monitoring activity carried out by each laboratory continuously to prevent or reduce the occurrence of errors/deviations so that correct inspection results are obtained. Quality Control on the Hematology Analyzer tool is important to carry out an analysis of accuracy, precision, and then evaluated using the Levey-Jennings chart which aims to determine any measurement deviations in the tool QC Level-N, QC Level-L, QC Level-H should be stored at 2-8°C before and after opening. Once opened, the product is stable for 7 days if returned immediately to the refrigerator after use. Research purposes is knowing the differences in material quality control inspection results on the hematology analyzer before and after going through the open stability period.

Methods: This research uses a descriptive observational study with a cross sectional design. This research was carried out in November-December 2024.

Result: The average results of the material quality control examination on the hematology analyzer before going through the open stability period were at low level WBC 3.47, RBC 2.64, HGB 6.2, HCT 18.07, and PLT 93.29, at a normal WBC level 7.06, RBC 4.40, HGB 11.87, HCT 33.24, PLT 219.71, at high level WBC 17.24, RBC 5.29, HGB 15.91, HCT 43.87, PLT 522.14. The average results of the material quality control examination on the hematology analyzer after passing through the open stability period were at low levels WBC 3.54, RBC 2.64, HGB 6.2, HCT 18.21, and PLT 91.29, at normal levels WBC 7.13, RBC 4.42, HGB 11.89, HCT 33.54, PLT 221.57, at high WBC level 17.26, RBC 5.30, HGB 15.96, HCT 44.07, PLT 524.71.

Conclusion: There was no difference in the results of material quality control checks on the hematology analyzer before and after going through the open stability period.

Keywords: Internal Quality Improvement, Quality Control, Hematology Analyzer

INTRODUCTION

Laboratory examinations, especially hematology, are widely used by doctor to establish a diagnosis, therefore a diagnostic examination must be carried out according to existing procedures so that the results are obtained. accurate, fast and reliable. This hematology examination is divided into two, namely routine blood tests and complete blood tests, parameters Hematology includes hemoglobin tests, leukocyte tests, erythrocyte tests, and platelets. (Riyanti, 2022).

Indication he did inspection hematology complete that is detecting existence abnormality cell blood like anemia, white blood cell disorders, allergies, blood clotting disorders due to abnormalities amount platelets as well as disturbance function hemostasis. Inspection hematology complete own a number of function that is detecting disturbance hematology Which is abnormality amount and function cell Sarah red, show abnormality function hemostasis, help to uphold diagnosis with see go on or the descent amount leukocytes and count the type (Saputra, 2022).

Hematology examination has experienced quite rapid progress over time. Hematology examinations generally use automatic *Hematology Analyzer tools* so that results can be issued quickly. The *Hematology Analyzer tool* is very easy to operate but still has tool limitations. The *Hematology Analyzer tool* can make mistakes in reading leukocyte cells if there are nucleated erythrocytes, giant platelets, platelet aggregation or agglutination, fibrin precipitation, protein or lipids, fragile red blood cells, malaria parasites, and samples are left for too long (Corporation, 2018; Restu Maharani & Dyah Astuti nd.).

Internal Quality Assurance (PMI) is a preventive and supervisory activity carried out by each laboratory continuously to prevent or reduce the occurrence of errors/deviations so that accurate examination results are obtained (Siregar, et. al., 2018; Stibis & Dyah Astuti nd.).

Quality control on the Hematology Analyzer tool is important to analyze accuracy and precision and then evaluate it using the *Levey-Jennings chart* which aims to... For know existence deviation measurement on the tool (Vis & Huisman, 2016)

The reliability of the instrument and reagents is monitored through Quality Control. By using control blood or control materials, the stability of the measured values is monitored over a period of time, and problems can be detected and prevented early. EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L, EIGHTCHECK-3WP-H should be stored at 2-8°C before and after opening. If treated like this, the unopened product is guaranteed to be stable until the expiration date stated on the package. Once opened, the product is stable for 7 days if returned to the refrigerator immediately after use. (Sysmex Corporation, 2012).

Quality Control must be performed before analyzing samples, after reagent replacement, after treatment, if there is any

doubt about the accuracy of the analytical values, as required by regulations. (Sysmex Corporation, 2012).

Based on the research of Rahayu Tri Ningsih, Tri Dyah Astuti S.ST, M.Kes, 2022 regarding the analysis of quality control in the examination of erythrocytes, leukocytes, and platelets with a hematology analyzer in the laboratory of Nyi Ageng Serang Hospital, where the results of the study showed that the three examinations had good precision and accuracy, while in the examination of leukocytes after being evaluated with a Levey-Jennings graph, the 13s rule was found to be caused by random error, the 31s and 8x rules were caused by systematic error.

Based on research by Adela Caesaria, Anik Handayati, Ayu Puspitasari, 2023 regarding the stability of three-level whole blood control stored at a temperature of 2-8°C using a hematology analyzer. Based on The test results obtained *p-values* for each parameter at all levels of the number parameter: erythrocytes, number leukocytes, hematocrit, hemoglobin and amount platelets. Based on results can concluded that No There is change stability *whole blood control* with storage for 10 weeks at a temperature of 2-8oC on the number of parameters *low* and *normal* leukocyte levels, *low* and *high* hematocrit levels, and all levels of the count parameters leukocytes, hemoglobin and amount platelets. While the hematocrit parameter is at a *normal* level and the number of *high* level leukocytes are present change stability.

Based on field observations still many have not know related to the open stability period of the control material

Based on this background, the author wants to conduct research on the Comparison of Material Quality Control Examination Results on Hematology Analyzer Tools Before and After Passing the Open Stability Period.

METHODS

Type and Design Study

Study This using descriptive observational studies with a *cross-sectional design*

Population and sample

Population

Population study This is all control material

Sample

Sample study This is all control material using total sampling technique.

Time and Place

Study will have implemented using a hematology analyzer. Time study This will implemented on November-December 2024

RESULTS AND DISCUSSION

RESULTS

The results of the study of the examination of the results of the material quality control on the hematology analyzer device before and after going through the open stability control period at low, normal, and high levels which was carried out in November-December 2024 using the hematology analyzer obtained the results with SPSS data processing.

3.1 Results Test Statistics

Univariate analysis was conducted to see the frequency distribution and bivariate analysis was conducted to determine whether or not there was a difference in the results of the material quality control examination on the hematology analyzer before and after passing the open stability period and to see the comparison of two variables, namely the independent and dependent variables. To see the comparison of the number of leukocytes, erythrocytes, hemoglobin, hematocrit, and platelets using the paired T test.

Paired Difference Test

Before conducting a bivariate test to see whether or not there is a difference in the results of the material quality control examination on the hematology analyzer before and after

passing the open stability period, a normality test is first carried out.

Normality Test

Table 1. Results of the Shapiro-Wilk Normality Test

		Sig.	Decision
Level 1	WBC_before	.086	Normally Distributed
	WBC_after	.609	Normally Distributed
	RBC_before	.752	Normally Distributed
	RBC_after	.215	Normally Distributed
	HGB_before	.	Not Normally Distributed
	HGB_after	.086	Normally Distributed
	HCT_before	.098	Normally Distributed
	HCT_after	.685	Normally Distributed
	PLT_before	.501	Normally Distributed
	PLT_after	.492	Normally Distributed
Level 2	WBC_before	.263	Normally Distributed
	WBC_after	.008	Not Normally Distributed
	RBC_before	.011	Not Normally Distributed
	RBC_after	.247	Normally Distributed
	HGB_before	<.001	Not Normally Distributed
	HGB_after	<.001	Not Normally Distributed
	HCT_before	.451	Normally Distributed
	HCT_after	.842	Normally Distributed
	PLT_before	.883	Normally Distributed
	PLT_after	.746	Normally Distributed
Level 3	WBC_before	.481	Normally Distributed
	WBC_after	.982	Normally Distributed
	RBC_before	.986	Normally Distributed
	RBC_after	.549	Normally Distributed
	HGB_before	.099	Normally Distributed
	HGB_after	.020	Not Normally Distributed
	HCT_before	.217	Normally Distributed
	HCT_after	.436	Normally Distributed
	PLT_before	.494	Normally Distributed
	PLT_after	.708	Normally Distributed

Based on the results of the Normality Test using the Shapiro-Wilk Test ($N < 50$), it is known that some data at each level are not normally distributed, namely at level 1 the HGB value data after treatment, at level 2 the WBC value after treatment, the RBC value before treatment, the HGB value before and after treatment. Therefore, the results of the normality test show that the research data is not normally distributed, the Hypothesis Test uses the Non-Parametric Test, namely the Wilcoxon Test.

Wilcoxon test

Level 1

Results of the Difference Test of Material Quality Control on the Hematology Analyzer Tool before and after passing the open

stability period using level 1, namely the low level on the material quality control.

Table 2. Results of the Difference Test of *Quality Control Materials* on the Hematology Analyzer Device Before and After Passing the *Open Stability Period* at Level 1

		Mean	SD	p-value
WBC	Before	3.47	0.07	0.102
	After	3.54	0.09	
RBC	Before	2.64	0.01	0.605
	After	2.64	0.01	
HGB	Before	6.2	0.00	0.317
	After	6.2	0.07	
HCT	Before	18.07	0.16	0.221
	After	18.21	0.18	
PLT	Before	93.29	4.62	0.352
	After	91.29	2.96	

Based on the results of the Wilcoxon Test, it is known that there is no significant difference in *the Material Quality Control* of the hematology analyzer tool as seen through the WBC, RBC, HGB, HCT, and PLT values at level 1. These results are shown through the p-value of each variable more than 0.05 (p-value > 0.05). So it can be concluded that the Open Stability Level 1 Period does not have a significant effect on *the Material Quality Control* of the Hematology Analyzer Tool. It is known that the average WBC value before treatment was $3.47 \times 10^3/\mu\text{L}$ and after treatment was $3.54 \times 10^3/\mu\text{L}$. As for the RBC value, it is known that the average value before treatment was $2.64 \times 10^6/\mu\text{L}$ and after treatment remained $2.64 \times 10^6/\mu\text{L}$. In the HGB value, it is known that the average value before treatment was 6.2 g/dl and after treatment remained 6.2 g/dl. The average value of HCT before treatment was 18.07% and after treatment was 18.21%. The average value of PLT before treatment was $93.29 \times 10^3/\mu\text{L}$ and after treatment was $91.29 \times 10^3/\mu\text{L}$.

Level 2

Results of the Difference Test of Material Quality Control on the Hematology Analyzer Tool before and after passing the open stability period using level 2, namely the normal level for material quality control.

Table 3. Results of the Difference Test of Material Quality Control on the Hematology Analyzer Device Before and After Passing the Open Stability Period at Level 2

		Mean	SD	p-value
WBC	Before	7.06	0.12	0.347
	After	7.13	0.09	
RBC	Before	4.40	0.03	0.343
	After	4.42	0.03	
HGB	Before	11.87	0.05	0.317
	After	11.89	0.03	
HCT	Before	33.24	0.35	0.309
	After	33.54	0.30	
PLT	Before	219.71	2.91	0.31
	After	221.57	5.12	

Based on the results of the Wilcoxon Test, it is known that there is no significant difference in *the Material Quality Control* of the hematology analyzer tool as seen through the WBC, RBC, HGB, HCT, and PLT values at level 2. These results are shown through the p-value of each variable more than 0.05 (p-value > 0.05). So it can be concluded that the Open Stability Level 2 Period does not have a significant effect on *the Material Quality Control* of the Hematology Analyzer Tool. It is known that the average WBC value before treatment was $7.06 \times 10^3/\mu\text{L}$ and after treatment was $7.13 \times 10^3/\mu\text{L}$. As for the RBC value, it is known that the average value before treatment was $4.40 \times 10^6/\mu\text{L}$ and after treatment remained $4.42 \times 10^6/\mu\text{L}$. In the HGB value, it is known that the average value before treatment was 11.87 g/dl and after treatment remained 11.89 g/dl. The average value of HCT before treatment was 33.24% and after treatment was 33.54%. The average value of PLT before treatment was $219.71 \times 10^3/\mu\text{L}$ and after treatment was $221.57 \times 10^3/\mu\text{L}$.

Level 3

Results of the Difference Test of Material Quality Control on the Hematology Analyzer Tool before and after passing the open stability period using level 3, namely the high level on material quality control.

Table 4. Results of the Difference Test of Quality Control Materials on the Hematology Analyzer Device Before and After Passing the Open Stability Period at Level 3

		Mean	SD	p-value
WBC	Before	17.24	0.22	0.739
	After	17.26	0.21	
RBC	Before	5.29	0.03	0.674
	After	5.30	0.02	
HGB	Before	15.91	0.06	0.414
	After	15.96	0.07	
HCT	Before	43.87	0.32	0.596
	After	44.07	0.33	
PLT	Before	522.14	5.99	0.345
	After	524.71	9.74	

Based on the results of the Wilcoxon Test, it is known that there is no significant difference in the *Material Quality Control* of the hematology analyzer tool as seen through the WBC, RBC, HGB, HCT, and PLT values at level 3. These results are shown through the p-value of each variable more than 0.05 (p-value > 0.05). So it can be concluded that the Open Stability Level 3 Period does not have a significant effect on the *Material Quality Control* of the Hematology Analyzer Tool. It is known that the average WBC value before treatment was $17.24 \times 10^3/\mu\text{L}$ and after treatment was $17.26 \times 10^3/\mu\text{L}$. As for the RBC value, the average value before treatment was $5.29 \times 10^6/\mu\text{L}$ and after treatment was $5.30 \times 10^6/\mu\text{L}$. In the HGB value, the average value before treatment was 15.91 g/dl and after treatment was 15.96 g/dl. The average value of HCT before treatment was 43.87% and after treatment was 44.07%. The average value of PLT before treatment was $522.14 \times 10^3/\mu\text{L}$ and after treatment was $524.71 \times 10^3/\mu\text{L}$.

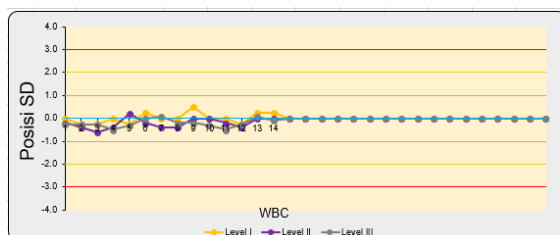


Figure 1. Levey-Jennings WBC chart
Based on Figure 4.1, it is known that the graph of the results of *material quality control* on the WBC parameter and the results obtained on the

WBC parameter at level 1 (*Low*), level 2 (*Normal*), and level 3 (*High*) are still within the range of $\pm 2\text{SD}$. This indicates that the *material quality control* level 1 (*Low*), level 2 (*Normal*), and Level 3 (*High*) are stable within 14 days.

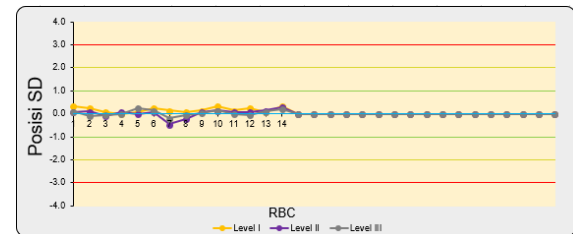


Figure 2. Levey-Jennings RBC Chart
Based on Figure 4.2, it is known that the graph of the results of *material quality control* on the RBC parameter and the results obtained on the RBC parameter at level 1 (*Low*), level 2 (*Normal*), and level 3 (*High*) are still within the range of $\pm 2\text{SD}$. This indicates that the *material quality control* level 1 (*Low*), level 2 (*Normal*), and level 3 (*High*) are stable within 14 days.

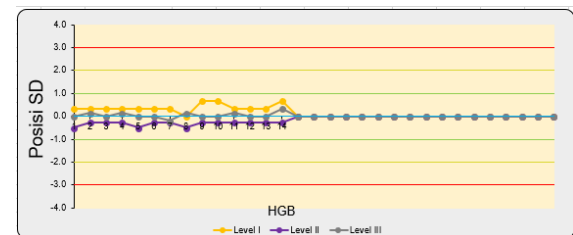


Figure 3. Levey-Jennings HGB Chart
Based on Figure 4.3, it is known that the graph of the results of *material quality control* on the HGB parameter and the results obtained on the HGB parameter at level 1 (*Low*), level 2 (*Normal*), and level 3 (*High*) are still within the range of $\pm 2\text{SD}$. This indicates that the *material quality control* level 1 (*Low*), level 2 (*Normal*), and level 3 (*High*) are stable within 14 days.

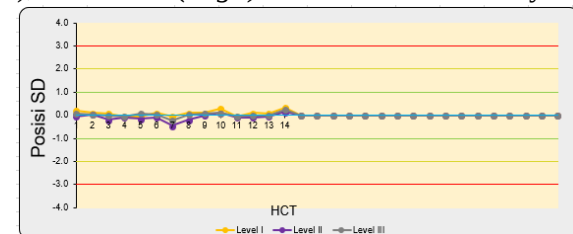


Figure 4. Levey-Jennings HCT graph
Based on Figure 4.4, it is known that the graph of the results of *material quality control* on the HCT parameter and the results obtained on the HCT parameter at level 1 (*Low*), level 2 (*Normal*), and level 3 (*High*) are still within the

range of $\pm 2SD$. This indicates that the material quality control level 1 (Low), level 2 (Normal), and level 3 (High) are stable within 14 days.

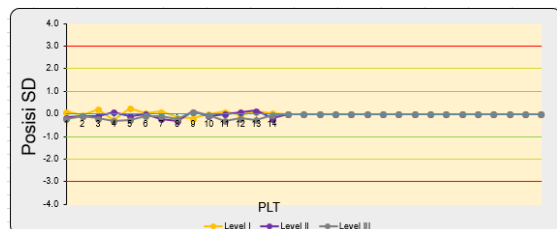


Figure 5. Levey-Jennings PLT Chart

Based on Figure 4.5, it is known that the graph of the results of material quality control on the PLT parameter and the results obtained on the PLT parameter at level 1 (Low), level 2 (Normal), and level 3 (High) are still within the range of $\pm 2SD$. This indicates that the material quality control level 1 (Low), level 2 (Normal), and level 3 (High) are stable within 14 days.

DISCUSSION

Research data on differences in the results of material quality control examinations on hematology analyzers before and after passing the open stability period which was carried out in November-December 2024 with three levels of material control, namely low, normal, and high level control using a hematology analyzer. The results of the statistical test P Value > 0.05 It means No There is difference Which significant impact on the results of the material quality control examination before and after passing through the open stability period.

Based on the results of the study, it is known that there is no significant difference in the Material Quality Control of the hematology analyzer tool as seen through the WBC, RBC, HGB, HCT, and PLT values at level 1. These results are shown through the p-value of each variable more than 0.05 ($p\text{-value} > 0.05$). So it can be concluded that the Open Stability Level 1 Period does not have a significant effect on the Material Quality Control of the Hematology Analyzer Tool. It is known that the average WBC value before treatment was $3.47 \times 10^3/\mu\text{L}$ and after treatment was $3.54 \times 10^3/\mu\text{L}$.

As for the RBC value, the average value before treatment was $2.64 \times 10^6/\mu\text{L}$ and after treatment remained $2.64 \times 10^6/\mu\text{L}$. The HGB value was known to have an average value before treatment of 6.2 g/dl and after treatment remained 6.2 g/dl. The average HCT value before treatment was 18.07% and after treatment was 18.21%. The average PLT value before treatment was $93.29 \times 10^3/\mu\text{L}$ and after treatment was $91.29 \times 10^3/\mu\text{L}$.

Based on the results of the study, it is known that there is no significant difference in the Material Quality Control of the hematology analyzer tool as seen through the WBC, RBC, HGB, HCT, and PLT values at level 2. These results are shown through the p-value of each variable more than 0.05 ($p\text{-value} > 0.05$). So it can be concluded that the Open Stability Level 2 Period does not have a significant effect on the Material Quality Control of the Hematology Analyzer Tool. It is known that the average WBC value before treatment was $7.06 \times 10^3/\mu\text{L}$ and after treatment was $7.13 \times 10^3/\mu\text{L}$. As for the RBC value, it is known that the average value before treatment was $4.40 \times 10^6/\mu\text{L}$ and after treatment remained $4.42 \times 10^6/\mu\text{L}$. In the HGB value, it is known that the average value before treatment was 11.87 g/dl and after treatment remained 11.89 g/dl. The average value of HCT before treatment was 33.24% and after treatment was 33.54%. The average value of PLT before treatment was $219.71 \times 10^3/\mu\text{L}$ and after treatment was $221.57 \times 10^3/\mu\text{L}$.

Based on the results of the study, it is known that there is no significant difference in the Material Quality Control of the hematology analyzer tool as seen through the WBC, RBC, HGB, HCT, and PLT values at level 3. These results are shown through the p-value of each variable more than 0.05 ($p\text{-value} > 0.05$). So it can be concluded that the Open Stability Level 3 Period does not have a significant effect on the Material Quality Control of the Hematology Analyzer Tool. It is known that the average WBC value before treatment was 17.24

$\times 10^3/\mu\text{L}$ and after treatment was $17.26 \times 10^3/\mu\text{L}$. As for the RBC value, the average value before treatment was $5.29 \times 10^6/\mu\text{L}$ and after treatment was $5.30 \times 10^6/\mu\text{L}$. In the HGB value, the average value before treatment was 15.91 g/dl and after treatment was 15.96 g/dl. The average value of HCT before treatment was 43.87% and after treatment was 44.07%. The average value of PLT before treatment was $522.14 \times 10^3/\mu\text{L}$ and after treatment was $524.71 \times 10^3/\mu\text{L}$.

This study is in line with the research of Adela Caesaria, Anik Handayati, Ayu Puspitasari, 2023 regarding the Stability of three-level whole blood control stored at a temperature of $2-8^\circ\text{C}$ using a hematology analyzer. Based on The test results obtained *p-values* for each parameter at all levels of the number parameter. erythrocytes, number leukocytes, hematocrit, hemoglobin and amount platelets. Based on results can concluded that No There is change stability *whole blood control* with storage for 10 weeks at a temperature of $2-8^\circ\text{C}$ on the number of parameters *low* and *normal* leukocyte levels, *low* and *high* hematocrit levels, and all levels of the count parameters leukocytes, hemoglobin and amount platelets. While the hematocrit parameter is at a *normal* level and the number of *high* level leukocytes are present change stability.

CONCLUSION

Results study Which has done about Differences in the results of the material quality control examination on the hematology analyzer before and after passing the open stability period, then you can conclude as follows:

The average results of the material quality control examination on the hematology analyzer before passing the open stability period at low levels WBC 3.47, RBC 2.64, HGB 6.2, HCT 18.07, and PLT 93.29, at normal levels WBC 7.06, RBC 4.40, HGB, 11.87, HCT, 33.24, PLT 219.71, at high levels

WBC 17.24, RBC 5.29, HGB 15.91, HCT 43.87, PLT $522.14 \times 10^3/\mu\text{L}$

The average results of the material quality control examination on the hematology analyzer after passing the open stability period at low level WBC 3.54, RBC 2.64, HGB 6.2, HCT 18.21, and PLT 91.29, at normal level WBC 7.13, RBC 4.42, HGB, 11.89, HCT, 33.54, PLT 221.57, at high level WBC 17.26, RBC 5.30, HGB 15.96, HCT 44.07, PLT 524.71

There is no difference in the results of the material quality control examination on the hematology analyzer before and after passing the open stability period.

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CONFLICT OF INTEREST

The authors declare there is no any conflict of interest during this study.

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